

No. 14-1525

United States Court of Appeals
for the Federal Circuit

BIOGEN IDEC MA, INC.,
Plaintiff-Appellant,

v.

JAPANESE FOUNDATION FOR CANCER RESEARCH;
BAYER PHARMA AG,
Defendants-Appellees.

Appeal from the United States District Court for the District of Massachusetts in
case no. 13-cv-13061, Judge F. Dennis Saylor IV.

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CERTIFICATE OF INTEREST

I, E. Anthony Figg, counsel for Appellant Biogen Idec MA Inc., certify the following:

1. The full names of the party represented by me is Biogen Idec MA Inc.
2. Biogen Idec MA Inc. is the real party in interest.
3. All parent corporations and publicly held companies that own 10 percent or more of the stock of this party are: Biogen Idec MA Inc. is a wholly owned subsidiary of Biogen Idec Inc. No corporation or publicly held company owns 10% or more of Biogen Idec Inc.'s stock.
4. The law firms and the partners and associates that appeared for these parties in the interference before the Patent Trial and Appeal Board and the district court litigation in the U.S. District Court for the District of Massachusetts, or are expected to appear in this Court are:

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TABLE OF ABBREVIATIONS

PTAB	Patent Trial and Appeal Board
BPAI	Board of Patent Appeals and Interferences
PTO	Patent and Trademark Office
AIA	Leahy-Smith America Invents Act, Pub. L. No. 112-29, 125 Stat. 284
TCA	Leahy-Smith America Invents Technical Corrections Act, Pub. L. 112-274, 126 Stat. 2456
hFIF	Recombinant human fibroblast interferon
EFD	Effective filing date
The '939 interference	Interference No. 105,939
The Fiers '843 application	U.S. Patent Application No. 08/253,843
The Sugano '757 application	U.S. Patent Application No. 08/463,757
The Fiers '609 application	U.S. Patent Application No. 06/250,609
The '096 interference	Interference No. 101,096
The '661 interference	Interference No. 105,661
The Fiers '646 application	U.S. Patent Application No. 08/471,646

STATEMENT REGARDING ORAL ARGUMENT

Biogen requests oral argument.

STATEMENT OF RELATED CASES

This case is related to Civil Action No. 1:13-CV-01489-CMH-TRJ brought in the U.S. District Court for the Eastern District of Virginia. That case involves the same parties and issues as this case and has been ordered transferred to this Court pursuant to 28 U.S.C. §1631.

JURISDICTIONAL STATEMENT

This Court has jurisdiction pursuant to 28 U.S.C. §1295(a)(1) to review a judgment of the District Court that it lacked subject-matter jurisdiction over the action brought by Biogen Idec MA, Inc. (“Biogen”). This Court also has jurisdiction pursuant to 28 U.S.C. §1295(a)(4)(A) (pre-TCA)¹ to review the decision U.S. Patent Trial and Appeal Board (“PTAB”) in the interference that is the subject of this case.

¹ This Court has jurisdiction over an appeal from a decision of the PTAB in an interference declared after September 15, 2012 pursuant to the version of 28 U.S.C. §1295(a)(4)(A) as it existed on September 15, 2012. Leahy-Smith America Invents Technical Corrections Act, Pub. L. 112-274, §1(k)(3), 126 Stat. 2456, 2457-58.

STATEMENT OF ISSUES

1. Whether the District Court erred in concluding that the AIA divested it of subject matter jurisdiction under 35 U.S.C. §146 and transferring the case to this Court pursuant to 28 U.S.C. §1631.
2. Only if this Court determines that the District Court lacked subject matter jurisdiction, whether the PTAB erred in concluding that interference estoppel bars Fiers (Biogen) from contesting the priority of claims that the Board itself refused to include in a prior interference.

STATEMENT OF THE CASE

This case originates from Interference No. 105,939 (the “’939 interference”) between two patent applications: U.S. Patent Application No. 08/253,843 to Walter Fiers (“Fiers”), filed on June 3, 1994 (“the Fiers ’843 application”) and U.S. Patent Application No. 08/463,757 to Sugano et al. (“Sugano”), filed on June 5, 1995 (“the Sugano ’757 application”), owned by Biogen and Japanese Foundation for Cancer Research (“JFCR”), respectively. Both applications claim the benefit of earlier applications, and in each case, the asserted chain of priority extends back to 1980.

The PTAB declared the ’939 interference on July 16, 2013 (JA00186-92) and at the same time *sua sponte* issued an Order to Show Cause (“the Order”) requiring Fiers to demonstrate why it would be able to prove an earlier date of

conception in the '939 interference when it could not do so in previous interferences between the two parties. JA02806-16. The Order also required Fiers to show why judgment should not be entered against it on the basis of issue preclusion and interference estoppel.

On October 3, 2013, the PTAB issued a decision concluding that Fiers was estopped from establishing priority in the '939 interference, because Fiers had not demonstrated that its claims were patentably distinct from the claims of the earlier interferences. JA00013-18. Following the PTAB's entry of judgment against Fiers, Biogen filed actions pursuant to 35 U.S.C. §146 (pre-AIA) against all of the entities identified as real parties in interest by Sugano during the interference proceedings (JFCR, Kyowa Hakko Kogyo, Toray Industries Ltd. and Bayer Pharma AG).² JA02000-24. The parties filed a stipulated motion to dismiss Kyowa Hakko Kogyo and Toray Industries Ltd. as dispensable parties and the District Court granted that motion. JA02120-22.

² Biogen first filed suit in the U.S. District Court for the District of Massachusetts. The defendants indicated that they intended to challenge personal jurisdiction in that court; therefore, Biogen filed a second precautionary action in the U.S. District Court for the Eastern District of Virginia. JA02322-43. Following the Massachusetts court's decision and transfer order, JFCR and Bayer Pharma AG moved the Virginia court to transfer to this Court. JA02620-24. Biogen did not oppose that motion, without prejudice to its right to challenge the correctness of the Massachusetts court's decision. The Virginia court granted the defendants' transfer motion. JA02723-24.

JFCR filed a motion to dismiss on grounds that the District Court lacked subject matter jurisdiction, based on the argument that the AIA eliminated §146 review of decisions in interferences declared after September 16, 2012. JA02062. Bayer Pharma AG later joined that motion. JA02301-02. On May 22, 2014, the District Court decided that it lacked subject-matter jurisdiction and transferred the case to this Court pursuant to 28 U.S.C. §1631. JA00001-12.

I. The Fiers GB Applications

The Fiers '843 application is a division of U.S. Patent Application No. 06/250,609, filed April 3, 1981 by Walter C. Fiers (“the Fiers '609 application”), which claims priority to British applications GB 8018701, filed June 6, 1980 (“the Fiers '701 GB application”), and British Application 8011306, filed April 3, 1980 (“the Fiers '306 GB application”). The Fiers '306 GB application is directed to recombinant DNA molecules and their use in producing structural genes for hFIF. JA04653-721 at JA04659. The Fiers '306 GB application discloses both the mature and precursor forms of hFIF.³ JA04669. Accordingly, the Fiers '306 GB application discloses the hFIF protein, means to express the functional hFIF

³ The difference between the two proteins lies in a 21-amino acid sequence found on the amino terminus of the precursor form of the protein. When hFIF is produced *in vivo*, this 21-amino acid sequence, referred to as a “signal peptide,” is cleaved from the precursor protein to result in the formation of the mature form.

protein, and the DNA that encodes the protein. JA04671-72, JA04679-83, JA05204.

II. The Fiers '609 Application Was Subject to Restriction

The Fiers '609 application was originally filed with claims directed to both the hFIF protein, and the DNA sequences that encode that protein. JA04406-536 at 516-22. The United States Patent and Trademark Office (the "PTO") determined that the hFIF protein was patentably distinct from the hFIF DNA and required restriction. JA04821-25. Fiers elected to prosecute the DNA claims in the '609 application and canceled the protein claims in compliance with the restriction requirement. Fiers subsequently elected to pursue the protein claims in a divisional application – the Fiers '843 application (the application involved in the '939 interference) – as permitted by 35 U.S.C. §121.⁴

III. The Previous Fiers v. Sugano Interferences

The show-cause order and judgment in the '939 interference were based on the PTAB's determination that party Fiers was estopped by the outcome of previous interferences from establishing priority with respect to the hFIF protein claims. Accordingly, a brief description of the earlier interferences is necessary.

⁴ The Fiers protein claims involved in the '939 interference have been pending for more than 30 years because of the PTO's suspension of their prosecution pending the resolution of other interferences.

A. Interference No. 101,096

Interference No. 101,096 (“the ’096 interference”) was declared on August 30, 1983 (redeclared on December 15, 1983), among the Fiers ’609 application, U.S. Patent Application No. 06/201,359, filed October 27, 1980 by Sugano et al. (“the Sugano ’359 application”), and U.S. Application No. 06/425,934, filed September 28, 1982 by Revel and Tiollais (“the Revel ’934 application”).

JA04813-20. The only Count in the ’096 interference was directed to a DNA encoding human fibroblast interferon, and specifically was directed to “[a] DNA which consists essentially of a DNA which codes for a human fibroblast interferon-beta polypeptide.” JA04816. The Count in the ’096 interference did not distinguish between the DNA encoding the precursor form, and the DNA encoding the mature form.

Prior to declaration of the ’096 interference, the PTO required restriction of the claims of the Fiers ’609 application, and Fiers was forced to cancel the claims directed to the hFIF protein. During the ’096 interference, Fiers filed a motion to add several proposed counts, including a count (Count 5) that was directed to hFIF protein. JA04867-85 at 67-69. However, the Board of Patent Appeals and Interferences (“the BPAI”) dismissed the Fiers Motion to Amend the Count, because Fiers was unable to demonstrate how the proposed Counts were supported

by the Sugano specification.⁵ JA04886-91. Upon filing the motion to add the proposed Counts, party Fiers acknowledged that it did not believe that the protein claims were patentable to Sugano, but was giving Sugano and the BPAI an opportunity to include that subject matter in the interference if they had a contrary view. JA04879-81.

The BPAI ultimately awarded priority to Sugano in the '096 interference, finding that Sugano had invented “a DNA sequence encoding a human fibroblast interferon-beta polypeptide” when it filed Japanese application 33931/80, on March 19, 1980 (“the Sugano JP priority application”). JA04892-06. The BPAI did not address priority as it relates to hFIF proteins in the '096 interference. This Court affirmed the BPAI’s decision. *Fiers v. Revel*, 984 F.2d 1164 (Fed. Cir. 1993).

B. Interference No. 105,661

Interference No. 105,661 (“the '661 interference”) was declared on March 4, 2009 between U.S. Patent Application No. 08/471,646 to Walter C. Fiers, filed on June 6, 1995 (“the Fiers '646 application”), and U.S. Patent Nos. 5,514,567, issued May 7, 1996 to Sugano et al. (“the Sugano '567 patent”), and 5,236,859, issued

⁵ The BPAI rules in effect at the time required a party proposing a new count in an interference to demonstrate that the proposed Count was supported by the other party’s specification. *See* 37 C.F.R. §1.231(a)(2) (1982); JA04890. The rules have since been changed, and that is no longer a requirement.

July 5, 1994, to Sugano et al. (“the Sugano ’859 patent”). JA04907-12. Like the Count in the ’096 interference, the Count in the ’661 interference was directed to hFIF DNA, specifically to a DNA sequence encoding mature hFIF. JA04910. Thus, the Count in the ’661 interference also did not include the hFIF protein.

The Fiers claims in the ’661 interference were directed to recombinant DNA molecules that hybridized to certain plasmids. But the BPAI determined that Fiers did not show that its claims were limited to DNA encoding mature hFIF.

JA04849-66 at 62. Fiers then requested permission to file motions to add claims limited to the mature form and claims limited to the precursor form, where only the claims to the mature form would correspond to the Count. JA05035-36. The BPAI denied Fiers permission to add claims, stating: (1) it was not necessary for the priority determination for Fiers to add claims that do not correspond to the Count, (2) Fiers had claims that did correspond to the Count, and (3) Fiers could pursue the claims it wished to add once it returned to *ex parte* prosecution. JA05043-52 at 46.

The BPAI construed the ’096 interference Count as directed to DNA encoding the complete sequence of hFIF and also construed Fiers’ claims in the ’096 interference as including DNA encoding the complete sequence of hFIF. The BPAI then determined that Fiers was estopped from contesting priority in the ’661 interference on the basis of the decision in the ’096 interference. JA04864.

C. The Sugano v. Goeddel Interferences

The Sugano '567 and '859 patents were also involved in two separate interferences with U.S. Application No. 07/374,311 to David V. Goeddel and Roberto Crea, filed June 30, 1989 ("the Goeddel '311 application"). Interference No. 105,334 ("the '334 interference") was directed to mature hFIF DNA, and Interference No. 105,337 ("the '337 interference") was directed to the mature hFIF protein. JA05053-65.

The BPAI granted Sugano the benefit of the Sugano JP priority application, but this Court reversed and found that the Sugano JP Priority application lacked written descriptive support for the mature hFIF DNA and the mature hFIF protein. *Goeddel v. Sugano*, 617 F.3d 1350, 1357 (Fed. Cir. 2010). JA04835-48. On remand, the BPAI determined that Goeddel derived the invention from Sugano and awarded priority to Sugano. JA03042.

IV. The Fiers v. Sugano '939 Interference

The '939 interference at issue in the present case was declared on July 16, 2013 between the Fiers '843 application and the Sugano '757 application. JA00186-92. The Fiers '843 application has been accorded the benefit of the Fiers '306 GB application. JA00190-91. The Sugano '757 application was accorded the benefit of the Sugano JP priority application. JA00190-91.

The '939 interference was declared with two Counts. JA00189. Both Counts are directed to recombinant human fibroblast interferon *proteins* ("hFIF"), and not to *DNA* encoding such proteins. Count 1 is to the mature form of the protein, and Count 2 is to the precursor form of the protein.

A. The Fiers Claims in Interference

The Fiers '843 application is a division of the Fiers '609 application, which contained claims to both the *DNA* encoding hFIF, and the hFIF *protein* itself. JA00044-160; JA04826. During prosecution of the Fiers '609 application, the PTO required restriction of the claims, holding that the claims directed to *DNA* were to a different invention than the claims directed to the *proteins*. JA004821-25. As a result, the protein claims in the '609 application were canceled, and are now being pursued in the Fiers '843 application that is the subject of the pending interference.

The pending Fiers '843 application has eight claims, all of which have been designated as corresponding to one or both of the '939 interference Counts. JA00190. The only independent claim in the Fiers '843 application is claim 16, which reads:

16. A recombinant polypeptide displaying the antiviral activity of human IFN- β , which activity is titratable by antibodies directed against human IFN- β , said polypeptide being free of human proteins other than human IFN- β and being produced by a non-human host transformed by a recombinant DNA molecule, said

recombinant DNA molecule characterized by a DNA sequence selected from the group consisting of:

- (a) DNA sequences which are capable of hybridizing to any of the DNA inserts of G-pBR322(Pst)/HF1F1, G-pBR322(Pst)/HFIF3 (DSM1791), G-pBR322(Pst)/HFIF6 (DSM 1792), and G-pBR322(Pst)/HFIF7 (DSM 1793) under hybridizing conditions of 0.75 M NaCl at 68° C and washing, conditions of 0.3 M NaCl at 68° C, and which code for a polypeptide displaying antiviral activity, and
- (b) DNA sequences which are degenerate as a result of the genetic code to the DNA sequences defined in (a);
 said DNA sequence being operatively linked to an expression control sequence in the recombinant DNA molecule.

JA02855.

B. The PTAB's Order to Show Cause

Immediately after declaring the '939 interference, the PTAB *sua sponte* issued an Order to Show Cause ("the Order") requiring Fiers to demonstrate why it would be able to prove an earlier date of conception in the '939 interference when it could not do so in previous interferences between the two parties. JA02806-16.

The PTAB issued the Order despite the fact that the earlier interferences were directed toward claims for DNA, while the current dispute concerns proteins. *See* JA02806-07. The Order also required Fiers to show why judgment should not be entered against it on the basis of issue preclusion and interference estoppel.

JA02807-09.

In its decision, the PTAB concluded that Fiers had not demonstrated that the *protein* claims of the current interference are patentably distinct from the *DNA* claims of the earlier '096 and '661 interferences. JA00017-18. Specifically, the PTAB concluded that “the knowledge of those skilled in the art regarding the genetic code would have rendered the polypeptides Fiers now claims to have been obvious over the subject matter lost in the previous interferences.” JA00016. The PTAB cited no evidence in support of that conclusion. JA00016.

The PTAB found Fiers' argument that the earlier restriction requirement in the parent '609 application is evidence of separate patentability was not persuasive. JA00014-15. The PTAB also found the declaration of separate interferences for the protein and DNA claims in the Sugano-Goeddel interferences was not indicative of the separate patentability of protein and DNA. JA00015. Finally, the PTAB found that Fiers' inability to add a count to the protein claims in the '096 interference is evidence that Fiers should be estopped from proceeding in the '939 interference. JA00016-17. For these reasons, the PTAB held that Fiers was estopped from proceeding in the '939 interference on the basis of interference estoppel. JA00017.

C. The §146 Actions

Following the PTAB's entry of judgment against Fiers, Biogen filed actions pursuant to 35 U.S.C. §146 (pre-AIA) against all of the entities identified as real-

parties-in-interest by Sugano during the interference proceedings (JFCR, Kyowa Hakko Kogyo, Toray Industries Ltd. and Bayer Pharma AG).⁶ JA02000-24. The parties filed a stipulated motion to dismiss Kyowa Hakko Kogyo, and Toray Industries Ltd. as dispensable parties and the District Court granted that motion. JA02049-151.

JFCR filed a motion to dismiss on grounds that AIA divested the District Court of subject matter jurisdiction, based on the argument that the AIA eliminated §146 review of decisions in interferences declared after September 16, 2012. JA02070. Bayer Pharma AG later joined that motion. JA02301-03. Both defendants also filed motions to dismiss based on lack of personal jurisdiction. JA02070; JA02088-92.

The District Court permitted briefing on all motions and held a hearing on May 2, 2014. JA20001-84. On May 22, 2014, the District Court decided that it lacked subject matter jurisdiction, but rather than dismissing the case, ordered that it be transferred to this Court pursuant to 28 U.S.C. §1631 in accordance with this Court's holding in *In re Teles AG Informationstechnologien*, 747 F.3d 1357 (Fed. Cir. 2014). JA00001-12.

⁶ Biogen also filed suit in the Eastern District of Virginia. *See*, FN 2, *supra*.

SUMMARY OF THE ARGUMENT

This case results from the erroneous decision of the District Court that Congress, in enacting the AIA, stripped the district courts of jurisdiction to review interference decisions of the PTAB. The opportunity to seek judicial review by district courts had existed for more than 170 years. Nevertheless, the District Court concluded that the AIA eliminated §146 review of interferences declared after September 16, 2012, yet reinstated it six months later for derivation proceedings, and that Congress made these changes without any legislative history or public comment or debate. The District Court concluded that the only avenue for judicial review in this case was a direct appeal to this Court pursuant to 35 U.S.C. §141.

The District Court reached this erroneous decision by misinterpreting key provisions of the AIA. The AIA provides for the transition of the U.S. patent system from a first-to-invent to a first-inventor-to-file (“first-to-file”) system. Despite its complexity, the AIA sets forth a coherent scheme for this transition, including the conduct and appeal of interferences that were pending at the time applicable provisions came into effect as well as for later-declared interferences.

The District Court erroneously concluded that AIA §6(f)(3)(C) governed this interference and that there was, accordingly, no right of appeal to the District Court. In fact, that provision is irrelevant to the ’939 interference, because it deals

only with interferences that were pending as of September 16, 2012, not interferences, such as the '939 interference, declared *after* September 16, 2012. Under the applicable transition provisions set forth in AIA §3(n)(1), this interference was declared and conducted pursuant to the pre-AIA version of 35 U.S.C. §135. Its review by a district court is therefore appropriate pursuant to the pre-AIA version of 35 U.S.C. §146. The District Court erred in construing the AIA otherwise.

Because the District Court erred in concluding that it lacked subject matter jurisdiction, Biogen requests that this Court vacate the District Court's transfer order and remand for further proceedings under §146.

If, however, this Court affirms the District Court's subject-matter-jurisdiction holding, then this case should be treated as a direct appeal of the PTAB's decision pursuant to 35 U.S.C. §141. For these reasons, Biogen also addresses the PTAB's errors in dismissing the underlying interference.

The '939 interference involved competing patent applications directed to recombinant human fibroblast interferon ("hFIF"), also known as β -interferon, a protein having valuable immunological and antiviral activities. After declaring the interference, the PTAB summarily determined – on an Order to Show Cause that the PTAB issued *sua sponte* – that Biogen was estopped from establishing priority of invention based on decisions in earlier interferences between the same parties.

In so doing, the PTAB improperly resolved material factual disputes and denied Biogen the opportunity to develop a complete record. Moreover, the PTAB concluded the Biogen claims in the '939 interference were not patentably distinct from the lost interference counts without citing to any evidence.

The PTAB also held that Biogen was estopped from proceeding in the '939 interference because it could have introduced the claims at issue in this interference in one of the two earlier interferences between the parties. That holding flatly contradicts both the reasoning and the result of the PTO's own prior rulings preventing Biogen from doing exactly that.⁷

Thus, if this Court reaches the merits of the interference at all, Biogen requests that the PTAB's judgment be vacated, and the case remanded so that Biogen can present its case on the merits.

ARGUMENT

I. Standard of Review

A. The District Court's Opinion

This Court reviews questions of subject-matter jurisdiction, a question of law, *de novo*. *ABB Inc. v. Cooper Indus., LLC*, 635 F.3d 1345, 1348 (Fed. Cir. 2011). The District Court's decision was based entirely on statutory construction,

⁷ The PTAB also ordered Fiers to explain why the doctrine of issue preclusion did not apply in this case. However, the PTAB decision does not address or rely on issue preclusion.

an issue of law that this Court reviews *de novo*. *NTP, Inc. v. Research in Motion*, 418 F.3d 1282, 1315 (Fed. Cir. 2005).

B. The PTAB's Opinion

Pursuant to the Administrative Procedure Act, the Board's legal determinations are reviewed without deference. *In re Zurko*, 258 F.3d 1379, 1384 (Fed. Cir. 2001). This Court reviews the issue of collateral estoppel, of which interference estoppel is one form, *de novo*. *Shell Petroleum, Inc. v. U.S.*, 319 F.3d 1334, 1338 (Fed. Cir. 2003). To the extent the PTAB's decision is equivalent to summary judgment, this Court also reviews summary judgment *de novo*. *Ohio Willow Wood Co. v. Alps South, LLC*, 735 F.3d 1333, 1341-42 (Fed. Cir. 2013).

II. The District Court Has Subject Matter Jurisdiction Over Biogen's Action for §146 Judicial Review of the PTAB's Decision in the '939 Interference

The AIA preserved the right of parties whose patent claims pre-date the implementation of the first-to-file amendments to bring actions for judicial review in district courts under 35 U.S.C. §146. The District Court erred in concluding otherwise by misconstruing the relevant statutory language and relying on other irrelevant sections of the AIA. The District Court's errors include:

- overlooking the clear language of AIA §3(n)(1) and misconstruing AIA §3(n)(2);
- overlooking AIA §7(a)(1) and its importance in understanding the proper application of AIA §3(n)(1);

- misperceiving the purpose of AIA §6 and misconstruing the effect of AIA §6(f)(3)(C);
- misunderstanding the purpose of the TCA §1(k)(3); and
- misunderstanding the PTO's interpretation of the relevant AIA sections.

Because the District Court committed legal error in holding that the AIA eliminated District Court review under §146, Biogen requests that this Court vacate the District Court's transfer order and remand for further proceedings under §146.

A. Overview of the Relevant AIA Provisions

AIA §3 contains the amendments to the patent statute that changed the U.S. patent system from a first-to-invent system to a first-to-file system. It also contains transition provisions that determine how to apply the first-to-file amendments to patents and patent applications filed under the first-to-invent system. For this reason, AIA §3 applies in this case.

AIA §6, by contrast, created the new post-grant review proceedings that enable a challenger to seek review of the patentability of granted patents. Section 6 includes one provision – §6(f)(3) – that on its face, applies only to a subset of interferences (those declared before September 2012) to which this interference, declared in July 2013, does not belong.

AIA §7 replaces the BPAI with the PTAB, but also permits any reference to the BPAI to be deemed a reference to the PTAB. AIA §7 also governs the

jurisdiction of this Court over direct appeals taken from proceedings before the PTO.

B. Under AIA §3(n)(1), the Pre-AIA Version of 35 U.S.C. §146 Applies

Congress recognized that it would not be appropriate to apply the new first-to-file provisions to a patentee or patent applicant who had filed a patent application under the first-to-invent regime. Section 3(n) of the AIA provides the mechanism for transitioning from first-to-invent to first-to-file without prejudicing those whose patents and patent applications have effective filing dates (“EFD”) before the effective date of the first-to-file amendments. *See Tobinick v. Olmarker*, 753 F.3d 1220, n.1 (Fed. Cir. 2014).

AIA §3(n) reads as follows:

3(n) EFFECTIVE DATE.—

(1) IN GENERAL.--Except as otherwise provided in this section, the amendments made by this section shall take effect upon the expiration of the 18-month period beginning on the date of the enactment of this Act, and shall apply to any application for patent, and to any patent issuing thereon, that contains or contained at any time--

(A) a claim to a claimed invention that has an effective filing date as defined in Section 100(i) of title 35, United States Code, that is on or after the effective date described in this paragraph; or

(B) a specific reference under section 120, 121, or 365(c) of title 35, United States Code, to any patent or application that contains or contained at any time such a claim.

(2) INTERFERING PATENTS.--The provisions of sections 102(g), 135, and 291 of title 35, United States Code, as in effect on the day before the effective date set forth in paragraph (1) of this subsection, shall apply to each claim of an application for patent, and any patent issued thereon, for

which the amendments made by this section also apply, if such application or patent contains or contained at any time--

(A) a claim to an invention having an effective filing date as defined in Section 100(i) of title 35, United States Code, that occurs before the effective date set forth in paragraph (1) of this subsection; or

(B) a specific reference under section 120, 121, or 365(c) of title 35, United States Code, to any patent or application that contains or contained at any time such a claim.

125 Stat. 284, 293.

Thus, Section 3(n) addresses three types of patents and patent applications:

(i) those in which *all* claims are entitled to an EFD *after March 16, 2013* (18 months after enactment of the AIA) (*see* 3(n)(1));

(ii) those in which *all* claims have an EFD *before March 16, 2013* (*see* 3(n)(1)); and

(iii) those that contain claims with EFDs *both before and after March 16, 2013* (*see* 3(n)(2)).

This case falls into the second category, because all of the claims in both of the interfering applications have EFDs *before* March 16, 2013.

1. AIA §3(n)(1) Governs the Transition to the First-to-File System

AIA §3(n)(1) has two effects on the implementation of the first-to-file amendments of AIA §3. First, it provides that the effective date of the amendments contained in AIA §3 was eighteen months after enactment, *i.e.*, March 16, 2013. That is the date on which the statutory language actually changed. Second, and equally important, §3(n)(1) specifies the patents and applications to

which the first-to-file amendments apply. It provides that “the amendments made by this section [3] . . . shall apply to any application for patent and to any patent issuing thereon, that contains or contained at any time . . . [a claim with an EFD on or after March 16, 2013].” This statutory language recognizes that there will be some applications to which the first-to-file amendments will not apply and thus sets up a dual system in which the old first-to-invent rules apply to some applications and the new first-to-file rules to others.⁸

The statutory scheme is clear: the amendments changing the U.S. patent system from first-to-invent to first-to-file are contained in AIA §3. Because the interference at issue in this case involves only patent applications having claims with EFDs before March 16, 2013, the *first-to-file amendments in AIA §3 do not apply*, and this interference is governed by the pre-AIA versions of the provisions of Title 35. The inapplicable first-to-file amendments include the amendments to 35 U.S.C. §§135 and 146 contained in AIA §§3(i) and 3(j) (125 Stat. 284, 289-90), respectively.

⁸ The District Court found that Biogen’s argument that the amended version of §146 would apply only to interferences involving patents and applications with EFDs after March 16, 2013, but the old version of Section 146 would “live on” for interferences involving patents and applications with EFDs before March 16, 2013 as creating a “highly unusual state of affairs.” JA00010. However, as both this Court (*see Tobinick, supra*) and the PTO (*see Section II.E infra*) have recognized, that is precisely the state of affairs that Congress envisioned, and the pre-AIA versions of §§ 102, 103, 134, 135, 145, 146, 154, 291 and 305 continue to “live on” for pre-March 16, 2013 patents and applications.

Because the first-to-file amendments do not apply to the interfering applications in the '939 interference, the PTAB had the authority to declare and conduct the interference.⁹ Pursuant to AIA §3(n)(1), the AIA §3(i) amendments to 35 U.S.C. §135 and the AIA §3(j) amendments to 35 U.S.C. §146 do not apply, because this interference only involves claims with EFDs before March 16, 2013. Thus, the PTAB had the authority to declare and conduct the '939 interference under the pre-AIA version of §135, and the District Court had jurisdiction to review the PTAB's decision under the pre-AIA version of §146.

2. Pursuant to AIA §7(a)(1) the BPAI Is Deemed to Be the PTAB in the pre-AIA Version of §146

Congress also recognized that the application of the pre-AIA versions of §§135 and 146 to post-AIA interferences required an additional fix. The pre-AIA versions of those statutes refer to the BPAI; however, effective on September 16, 2012, 35 U.S.C. §6 was amended to eliminate the BPAI and to replace it with the

⁹ The District Court erroneously concluded that AIA §3(n)(2) provides the basis for the PTAB to continue to declare interferences. JA00007-8. As discussed below in Section II.C.1. this conclusion was based on the District Court's failure to recognize that §3(n)(2) deals only with patents and patent applications that contain *both* claims with EFDs after March 16, 2013 and claims with EFDs before March 16, 2013. Neither of the applications involved in the present interference contain such mixed claims; therefore, §3(n)(2) is inapplicable to this case. The PTAB's authority to declare and conduct the '939 interference is found in AIA §3(n)(1), not §3(n)(2).

PTAB. *See* AIA §7(a)(1) (establishing PTAB); AIA §7(e) (making amendments of §7 effective one year after AIA enactment, *i.e.*, on September 16, 2012).

Therefore, interferences like the '939 interference, declared *after* September 16, 2012 would be conducted before the PTAB, and judicial review of such interferences would be of PTAB decisions. Recognizing that the pre-AIA versions of the statutes referred to the BPAI but that post-September 16, 2012 interferences would be conducted and decided by the PTAB, Congress provided in AIA §7(a)(1) that “[a]ny reference in any Federal law, Executive order, rule, regulation or delegation of authority, or any document of or pertaining to the Board of Patent Appeals and Interferences is deemed to refer to the Patent Trial and Appeal Board.” Pursuant to AIA §7(e), this provision applies only to interferences declared on or after September 16, 2012. On January 14, 2013, Section 6 of Title 35 was further amended by TCA §1(k)(3), and that section also contained a provision that the PTAB shall be deemed to be the BPAI with respect to interferences declared after September 16, 2012. The District Court’s statement that “there is no longer a BPAI to adjudicate the dispute” as a basis for rejecting the applicability of a AIA §3(n)(1) was error and was based on its overlooking the effects of AIA §7(a)(1) and TCA §1(k)(3). JA00007-8. It is for this reason that the transition provisions in AIA §3(n) apply only to interferences declared after September 16, 2012.

Thus, AIA §3(n)(1) provided for the conduct of the '939 interference before the PTAB pursuant to the pre-AIA version of §135, and it provided for district court review of the PTAB's decision pursuant to the pre-AIA version of §146. The District Court erred as a matter of law in concluding that it lacked subject matter jurisdiction.

C. The District Court Erred in Concluding that AIA §6 Made Judicial Review of Interference Decisions Available Only for Interferences Commenced Before September 16, 2012

The District Court concluded that when the amendments in AIA §3 took effect on March 16, 2013, §3(n)(1) “[swept] away the old versions of the [patent] law except as specifically provided in the AIA.” JA00007. The District Court then reasoned:

AIA §3(n)(2) provided that interferences under the pre-AIA Section 135 would continue, but there no longer was a BPAI to adjudicate the dispute and no right of appeal. AIA §6 partially filled that gap, but only for interferences commenced before September 16, 2012 (“pending interferences”).

JA00007-8 (citing AIA §6(f)(3)(C)). Based on its reading of AIA §6(f)(3)(C), the District Court concluded that “interferences commenced before September 16, 2012 had a venue at the PTAB and the right to appeal to the Federal Circuit or the Eastern District of Virginia as if they were derivation proceedings.”¹⁰ According

¹⁰ Another error in the District Court’s opinion is that the AIA changed the venue for §146 actions to the U.S. District Court for the Eastern District of Virginia (“EDVA”). *See* JA00008. That is an overstatement. All the AIA did was change

to the District Court, the AIA, as originally enacted, made no mention of venue or appeal of interferences declared after September 16, 2012. JA00008. It then concluded that the TCA later restored the right to appeal to the Federal Circuit under §141, but not the right to seek judicial review by a district court under §146. JA00009-10. The District Court’s analysis contains numerous errors.

1. The District Court Misinterpreted AIA §3(n)(2)

The root of the District Court’s erroneous interpretation appears to be its view that AIA §3(n)(2) provided that:

interferences under the pre-AIA §135 would continue, but that there no longer was a BPAI to adjudicate the dispute and no right of appeal. AIA §6 partially filled that gap, but only for interferences commenced before September 16, 2012 (“pending interferences”).

JA00007-8. In reaching these conclusions, the District Court overlooked AIA §7(a)(1) (providing that statutory references to BPAI are deemed to be to the PTAB) and misconstrued AIA §3(n)(2), overlooking an important clause in that section. It also misunderstood the purpose and effect of AIA §6 in suggesting that §6 was intended to “partially fill” a gap in AIA §3(n)(2).

To the contrary, it is because of the transition rule specified in AIA §3(n)(1) – not §3(n)(2) – that interferences under pre-AIA §135 will continue to be

the default venue from the District Court for the District of Columbia to the EDVA. AIA §9 (125 Stat. 284, 316). Actions may still be brought in any district court having jurisdiction over the parties.

declared for years to come. AIA §3(n)(1) provides that interferences involving patents and patent applications with EFDs before March 16, 2013, like the '939 interference in this case, are governed by the pre-AIA statutes, including §§135 and 146.

The District Court erroneously rejected Biogen's interpretation of AIA §3(n)(1) on the grounds that "[t]he AIA specifically provides [in AIA §3(n)(2)] which sections of the law will still apply: §§102(g), 135 and 291." JA00007. In reaching this erroneous interpretation, the District Court overlooked an important part of AIA §3(n)(2), the phrase, "for which the amendments made by this section also apply." The import of that phrase is that AIA §3(n)(2) applies only to patent applications having *both* (i) claims with EFDs before March 16, 2013 *and* (ii) claims with EFDs after March 16, 2013.¹¹ For this unique subset of applications, Congress expressly preserved the right to initiate interference that would not

¹¹ For such unique patent applications in which the applicant seeks to benefit from both the old and the new laws, Congress appears to have limited the right to appeal. This fact was recognized in the PTO's comments explaining its implementing rules: "That is because if the involved application contains a claim satisfying the terms of §3(n)(1) of the [AIA] e.g., a continuation-in-part application) then §3(j) of the [AIA] – changing 35 U.S.C. 146 from review of an 'interference' to review of 'a derivation proceeding' – applies, and district court review of a decision arising out [of] an interference proceeding under 35 U.S.C. 135 will not be available." Rules of Practice for Trials Before the PTAB and Judicial Review of PTAB Decisions, 77 Federal Register 6,879, 6,891 (Feb. 9, 2012). Whether and the extent to which AIA §3(n)(2) limits the right of appeal for interferences involving mixed claims is not an issue in this case, because neither of the involved applications contains such mixed claims.

normally be available, because the amendments made by AIA §3 would have eliminated that right. However, §3(n)(2) has no effect on interferences like the '939 interference that involve applications containing *only* claims with an EFD before March 16, 2013.

In short, contrary to the District Court's interpretation, AIA §3(n)(2) does not limit the general applicability of AIA §3(n)(1) or its applicability in this case, but instead applies only to interferences involving patent applications containing mixed claims with EFDs before and after the critical date. In addition, the District Court's conclusion that AIA §3(n)(2) provided the basis for the continued declaration and prosecution of interferences under the pre-AIA §135 is wrong. The reason that such interferences continue to be declared is that under AIA §3(n)(1), the amendments to §135 contained in AIA §3(i) do not apply to interferences involving patents or applications with EFDs before March 16, 2013 (just as the amendments to §146 contained in AIA Section 3(j) do not apply to such interferences).

2. AIA §6(f)(3)(C) Does Not Apply to the '939 Interference

The District Court's conclusion that the only judicial review preserved under 35 U.S.C. §146 is that provided by AIA §6(f)(3)(C) results both from its misunderstanding of AIA Section 3(n) as discussed above, and its failure to recognize the purpose and the effect of AIA §6(f). AIA §6 deals with post-grant

proceedings, and §6(f)(3) deals incidentally with interferences that were pending when the §6 amendments took effect. AIA §6(f)(3)(C) is a subpart of a provision governing the effective date and implementation of the new post-grant review (“PGR”) procedures established in subsection (d) of AIA §6. It is not concerned with the implementation of the first-to-file provisions of AIA §3 that are at issue in this case.

AIA Section 6(f) (125 Stat. 284, 311) reads as follows:

(f) REGULATIONS AND EFFECTIVE DATE.--

(1) REGULATIONS.--The Director shall, not later than the date that is 1 year after the date of the enactment of this Act, issue regulations to carry out chapter 32 of title 35, United States Code, as added by subsection (d) of this section.

(2) APPLICABILITY.--

(A) IN GENERAL.--The amendments made by subsection (d) shall take effect upon the expiration of the 1–year period beginning on the date of the enactment of this Act and, except as provided in section 18 and in paragraph (3), shall apply only to patents described in section 3(n)(1).

(B) LIMITATION.--The Director may impose a limit on the number of post-grant reviews that may be instituted under chapter 32 of title 35, United States Code, during each of the first 4 1–year periods in which the amendments made by subsection (d) are in effect.

(3) PENDING INTERFERENCES.--

(A) PROCEDURES IN GENERAL.--The Director shall determine, and include in the regulations issued under paragraph (1), the procedures under which an interference commenced before the effective date set forth in paragraph

(2)(A) is to proceed, including whether such interference--

(i) is to be dismissed without prejudice to the filing of a petition for a post-grant review under chapter 32 of title 35, United States Code; or

(ii) is to proceed as if this Act had not been enacted.

(B) PROCEEDINGS BY PATENT TRIAL AND APPEAL BOARD.--For purposes of an interference that is commenced before the effective date set forth in paragraph (2)(A), the Director may deem the Patent Trial and Appeal Board to be the Board of Patent Appeals and Interferences, and may allow the Patent Trial and Appeal Board to conduct any further proceedings in that interference.

(C) APPEALS.--The authorization to appeal or have remedy from derivation proceedings in sections 141(d) and 146 of title 35, United States Code, as amended by this Act, and the jurisdiction to entertain appeals from derivation proceedings in section 1295(a)(4)(A) of title 28, United States Code, as amended by this Act, shall be deemed to extend to any final decision in an interference that is commenced before the effective date set forth in paragraph (2)(A) of this subsection and that is not dismissed pursuant to this paragraph.

This section provides that PGR is generally available for patents having EFDs after March 16, 2013 (*see* §6(f)(2)(A) – “shall apply only to patents described in section 3(n)(1)”). However, it makes two exceptions: one for covered business method patents (AIA §18) and the other for patents described in §6(f)(3). The patents described in §6(f)(3) are those that are involved in interferences commenced before and pending as of September 16, 2012 (one year after AIA enactment). AIA §6(f)(3)(A) gives the Director authority to dismiss such an interference in favor of a PGR, even though the patent would not otherwise have an EFD making it eligible for PGR.

The dismissal option is discretionary, and the Director also has the right to allow such an interference to proceed. However, Congress recognized that after

September 16, 2012 and until the amendments of AIA §3 went into effect on March 16, 2013, §§135, 141 and 146 all referred to the BPAI. As discussed above, pursuant to AIA §7(a)(1), the BPAI ceased to exist on September 16, 2012 and was replaced by the PTAB. Therefore, §6(f)(3)(B) provides that the PTAB shall be deemed to be the BPAI and that interferences declared before September 16, 2012 can be conducted before the PTAB.

Similarly, §6(f)(3)(C) provides for judicial review of PTAB decisions in such pre-September 16, 2012 interferences in the Federal Circuit (§141) and district courts (§146) as amended by the AIA, as if they were derivation proceedings. These provisions were necessary, because AIA §7(a)(1) (and, subsequently, TCA §1(k)(3)) did not fix the problem of the statutes' referring to the BPAI as they did for AIA §3(n)(1). AIA §7(a)(1) and TCA §1(k)(3) apply only to interferences declared on or after September 16, 2012, whereas §§6(f)(3)(B) and (C) apply to interferences declared before September 16, 2012. Thus, AIA §6(f)(3)(C) and AIA §3(n)(1) neither conflict with each other, nor are they redundant. They complement one another by addressing interferences declared during different time periods and under different circumstances. AIA §6(f)(3)(C) deals with interferences that were pending as of September 16, 2012 – well before the effective date of the first-to-file amendments – whereas AIA

§3(n)(1) deals with implementation of the first-to-file amendments, including the amendments to §135 and §146.

Because §6(f)(3)(C) applies only to interferences commenced before September 16, 2012, the District Court inferred that there was no right of §146 judicial review for interferences declared after that date. JA00008. That inference was wrong. AIA §3(n)(1), together with AIA §7(a)(1), provides for judicial review of interferences declared after September 16, 2012, but not of interferences declared before that date (because AIA §7(a)(1) and, subsequently, TCA §1(k)(3) do not provide that the BPAI shall be deemed to be the PTAB for interferences declared before September 16, 2012). Therefore, Congress had to make special provision for the conduct of pre-September 16, 2012 interferences and their appeal. It did so in AIA §§6(f)(3)(B) and (C).

Because the interference involved in this case was declared after September 16, 2012, its conduct before the PTAB under §135 and its judicial review under §146 are governed by the pre-AIA versions of those statutes pursuant to AIA §3(n)(1). AIA Section 6(f)(3)(C) has no applicability to this case.

D. The District Court Misunderstood the Technical Corrections Act

The District Court's conclusion that the TCA confirms that judicial review under 35 U.S.C. §146 was abolished after September 16, 2012, because it restored only §141 review by the Federal Circuit, ignores the fact that §146 review did not

need to be restored because it was not inadvertently eliminated. Federal Circuit review of interferences declared after September 16, 2012 was inadvertently eliminated by the original version of the AIA. Specifically, AIA §7(c), which amended 35 U.S.C. §141, failed to include interferences in the list of proceedings subject to Federal Circuit review. Importantly, the AIA amendments eliminating review of interferences under §141 took effect on September 16, 2012. AIA §7(e), 125 Stat. 284, 315. In addition, unlike the amendments made by §3, the amendments made by §7 apply to all proceedings initiated after September 16, 2012, regardless of whether those proceedings involve patents or patent applications with claims having EFDs before March 16, 2013.

In contrast with this inadvertent omission of §141 Federal Circuit review, the AIA preserved §146 judicial review by district courts. Specifically, AIA §3(n)(1), together with AIA §7(a)(1), preserved §146 judicial review under the pre-AIA version of §146 for interferences declared on or after September 16, 2012. AIA §6(f)(3)(C) preserved §146 judicial review by district courts of decisions and interferences commenced before September 16, 2012. Thus, there was no reason for Congress to restore §146 review in the TCA. The District Court erred in drawing a negative inference that the TCA's failure to mention §146 review reflected an intent by Congress to eliminate §146 judicial review for interferences declared after September 16, 2012.

The District Court's determination that the right of judicial review embodied in §146 – a right that had existed in one form or another since 1836 – has been eliminated is remarkable. *Troy v. Samson Mfg. Corp.*, No. 2013-1565, 2014 U.S. App. LEXIS 13147, *10-11 (Fed. Cir. July 11, 2014) (discussing the history of §146). It is inconceivable that Congress would eliminate such an important right of appeal through negative inference without any legislative history or public commentary. Indeed, even under the AIA, district court review under §146 remains available for derivation proceedings. That district court review remains available underscores Congress' recognition that such review is an important right that was not eliminated by the AIA. Moreover, it evidences the irrationality of the District Court's determination in that Congress eliminated a long-standing avenue of appeal in September 2012, only to restore it in March 2013.

E. The District Court's Interpretation of AIA §3(n)(1) Is Contrary to That of the PTO

Biogen's interpretation and application of AIA §3(n)(1) is entirely consistent with and supported by that of the PTO. Upon enactment of the AIA, the PTO adopted rules for implementing the new statute. The PTO commentary that accompanied its proposed rules contained the following statement:

Regarding judicial review of Board decisions arising out of such interferences, §7(c) and (e) of the [AIA] makes review by the Federal Circuit available under 35 U.S.C. 141 only for proceedings commenced before September 16, 2012. Similarly, §3 of the [AIA] makes review of interference decisions by a District Court under 35

U.S.C. 146 available only if the provisions of §3(n)(1) of the [AIA] are not satisfied. That is because if the involved application contains a claim satisfying the terms of §3(n)(1) of the Leahy-Smith America Invents Act (e.g., a continuation-in-part application), then §3(j) of the Leahy-Smith America Invents Act-changing 35 U.S.C. 146 from review of “an interference” to review of “a derivation proceeding”-applies, and district court review of a decision arising out [of] an interference proceeding under 35 U.S.C. 135 will not be available. To the extent that an interference proceeding under 35 U.S.C. 135 is available and judicial review of that decision is available, the Office will continue to apply the regulations as they existed when the [AIA] was enacted (or as subsequently modified prior to July 1, 2012) to those proceedings. Lastly, note that certain interferences may be deemed to be eligible for judicial review as though they were derivation proceedings. *See* §6(f)(3) of the [AIA].

77 Federal Register 6,879, 6,891.¹² The PTO’s interpretation is clear: under AIA §3, “review of interference decisions by a District Court under 35 U.S.C. 146” *is* available if the provisions of §3(n)(1) are not satisfied. In this case, the provisions of §3(n)(1) are not satisfied, because only patent applications filed before March 16, 2013 are involved. Accordingly, under the PTO’s interpretation, §146 judicial review of the PTAB’s decision in the ’939 interference is available under the pre-AIA version of §146. The PTO’s final rule reflects this comment and states, “where available, judicial review of decisions arising out of interferences declared pursuant to 35 U.S.C. 135 continue to be governed by the pertinent regulations in effect on July 1, 2012.” 37 C.F.R. §90.1.

¹² Nearly identical language accompanied the final rules. 77 Federal Register 48,612, at 48,625 (Aug. 14, 2012).

The District Court improperly discounted these unambiguous statements based on the PTO's use of the qualifiers "where available" and "to the extent," concluding that these qualifiers meant that such judicial review was only available for pre-September 16, 2012 interferences. JA00010-11. This interpretation of the PTO's position is misguided. It ignores the plain language of the final rule and the accompanying comments, and also ignores the fact that in the opening sentence of its comments, the PTO recognized that the AIA had eliminated Federal Circuit review of post-September 16, 2012 interferences under §141. Congress later corrected that mistake and restored Federal Circuit review with the TCA, but at the time of the proposed PTO rules and comments, the TCA had not yet restored it. *See* Section II.D, *supra*. Thus the PTO's qualifiers, "where available" and "to the extent that," logically refer to the fact that judicial review by the Federal Circuit under §141 was not available at the time the PTO adopted its rules.¹³

The District Court commented that the PTO cannot establish an Article III court's subject matter jurisdiction through rule-making. JA00011. But that

¹³ The PTO comments also correctly acknowledge that §146 review is available only if the provisions of AIA §3(n)(1) are not satisfied (*i.e.*, for patents and applications with EFDs before March 16, 2013) and that such review is not available for interferences involving a patent application with mixed claims (AIA §3(n)(2)). Thus, it is clear that the PTO recognized that judicial review is not available in every circumstance. The District Court's inference that the qualifiers "to the extent" and "where available" abrogated the plain meaning of the PTO's comments and rules was incorrect. JA00010.

comment misses the point. Establishing courts' subject matter jurisdiction was not the purpose of the rules, nor is that Biogen's point in referring to the rules and accompanying commentary. The PTO was required to adopt rules to govern its own conduct. It is essential that the PTO be able to determine when and if an effective appeal or action for judicial review of an interference decision has been filed so as to be able to handle the applications before it.

The PTO is an expert agency charged with administering the patent laws. Although the PTO's interpretation may not be entitled to *Chevron* deference in this case, that interpretation by the government agency charged with implementing the provisions of the AIA is persuasive support of Biogen's identical interpretation.

For the foregoing reasons, the District Court erred in concluding that it did not have subject matter jurisdiction over the action brought by Biogen. Accordingly, Biogen requests that the District Court's order transferring the case to this Court pursuant to 28 U.S.C. §1631 based on its erroneous decision on subject-matter jurisdiction be vacated and the case be remanded to the District Court for substantive review under the pre-AIA version of 35 U.S.C. §146.

III. The PTAB Erred in Determining that Interference Estoppel Applies to Fiers in the '939 Interference

In entering final judgment against Fiers on a show-cause order, the PTAB committed clear legal error by improperly resolving material factual disputes on the critical issue of patentable distinctness between recombinant hFIF proteins and

hFIF DNA.¹⁴ The PTAB resolved this factual dispute without any supporting evidence.

The PTAB also erred as a matter of law in concluding that Fiers was barred by principles of interference estoppel from establishing priority with respect to hFIF proteins. Fiers' inability to include the hFIF protein subject matter in the earlier interferences was entirely the result of earlier PTO rulings with which Fiers was bound to comply. Fiers is now in a "Catch 22" situation as a result of the PTAB's disagreement with earlier PTO decisions. This Court should vacate this unfair result, and remand this case to the PTAB for further proceedings.

A. Legal Standards Regarding Interference Estoppel

Interference estoppel prevents a losing party in a previous interference between the same parties from making any claim that is not patentably distinct from claims corresponding to the counts in issue in the previous interference. *In re Deckler*, 977 F.2d 1449, 1452 (Fed. Cir. 1992) ("[T]his court has applied Interference estoppel to bar the assertion of claims for inventions that are

¹⁴ The PTAB effectively granted summary judgment to Sugano. *See Huston v. Ladner*, 973 F.2d 1564, 1570 (Fed. Cir. 1992) (Newman, J., dissenting) ("Mr. Cohen's affidavit was filed in response to the Order to Show Cause why summary judgment should not be entered. Such evidence "is to be believed, and all justifiable inferences are to be drawn in his favor", *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 255 (1986), for no less deference than is afforded under Fed. R. Civ. P. 56(c)"); *see also Hahn v. Wong*, 892 F.2d 1028, 1032 (Fed. Cir. 1989) (noting that on an Order to Show Cause, a party need only establish a *prima facie* case of priority).

patentably indistinct from those in an Interference that the applicant had lost.”) Interference estoppel does not apply to cases in which the subject matter of the Counts are patentably distinct. *In re Kroekel*, 803 F.2d 705, 710 (Fed. Cir. 1986) (“If [the claim] were patentably distinct from the lost count, it could not be denied to [the Applicant] on the sole ground of interference estoppel.”). In addition, the applicability of interference estoppel “should be decided on the facts of each case with reference to principles of equity.” *Id.* at 709.

B. The Protein Claims are Patentably Distinct from DNA Claims

1. The PTAB Provided no Authority for its Conclusion Regarding the Knowledge of One of Ordinary Skill

The PTAB erred in determining that the protein claims of the Fiers ’843 application are not patentably distinct from the DNA claims that were the subject of the earlier interferences. As a result, interference estoppel cannot apply, and Biogen requests that the PTAB’s judgment be vacated and remanded.

In support of its determination, the PTAB stated only that “the Order to Show Cause indicates that the knowledge of those of skill in the art regarding the genetic code would have rendered the polypeptides Fiers now claims to have been obvious over the subject matter lost in the previous interferences.” JA00016. But the PTAB cites no authority or evidence for this erroneous and overly broad generalization.

The PTAB's failure to support this finding is in stark contrast to the previous admonishment by this Court that when the PTAB relies on what it asserts to be the general knowledge of one of skill in the art, "that knowledge must be articulated and placed on the record." *In re Lee*, 277 F.3d 1338, 1345 (Fed. Cir. 2002).

"'Common knowledge and common sense,' even if assumed to derive from the agency's expertise, do not substitute for authority when the law requires authority."

Id. Thus, the PTAB cannot rely on conclusory statements, and must set forth the rationale upon which it relies. *Id.* Indeed, this Court has been clear that "the Board cannot simply reach conclusions based on its own understanding or experience—or on its assessment of what would be basic knowledge or common sense. Rather, the Board must point to some concrete evidence in the record in support." *In re Zurko*, 258 F.3d at 1386 (concluding that an "assessment of basic knowledge and common sense" of the prior art was lacking in substantial evidence). Given the PTAB's failure to support its conclusory assertion that a person of ordinary skill in 1980 would have considered the Fiers protein claims obvious in view of the DNA claims of the previous interferences, the PTAB's assertion should be set aside.

The PTAB's error in relying on what appears to be "common knowledge" is compounded by the evidence actually before it. The PTAB stated that "Fiers does not contest" that "the knowledge of those of skill in the art regarding the genetic

code would have rendered the polypeptides Fiers now claims to have been obvious over the subject matter lost in the previous interferences.” JA00016. But the material facts submitted to the PTAB and cited by it elsewhere demonstrate the opposite. Fiers did in fact contest the conclusion that the protein claims in the present interference would have been obvious in light of the knowledge regarding the genetic code and the prior interference as of 1979-1980. JA03039-42; JA05201-03 (Dr. Jackson explaining the Sugano application does not disclose how to express hFIF even with the DNA encoding the immature protein). Moreover, Sugano failed to offer a competing declaration. The PTAB’s failure to acknowledge, much less address, the factual dispute renders its decision wrong as a matter of law.

2. Fiers’ Claims Are Directed to Functional Proteins

The PTAB appears to have based its holding that the protein and DNA claims are not patentably distinct on its simplistic view that a person of ordinary skill could have conceived or written down the amino acid sequence of hFIF protein based on the genetic code and the nucleotide sequence of hFIF DNA that was the subject of the counts of the earlier interferences. In addition to being wrong as a matter of law in view of the conflicting evidence before it, and its failure to substantiate its conclusory assertion of obviousness with evidence, the PTAB’s conclusion is also wrong as a factual matter.

The invention of the claims corresponding to the '939 interference Counts is not a mere amino acid sequence. The Fiers claims are directed to a functional recombinant human protein, *i.e.*, the claimed protein has biological activity (or, in the case of the precursor form, is converted to the active form upon enzymatic cleavage of the 21-amino acid signal peptide). A functional protein is not merely a string of letters on a page. It is instead a complex chemical entity having, in addition to the primary amino acid sequence, complex three-dimensional structure. This three-dimensional structure is critical to the desired biological activity of the protein. The recombinant protein can be processed and folded into a myriad of different configurations depending on particular conditions, and most of these configurations are not functional. *See In re O'Farrell*, 853 F.2d 894, 896-99 (Fed. Cir. 1988) (describing proteins, the relationship between DNA and proteins, and the difficulties of expressing proteins). Importantly, obtaining a functional protein with the correct three-dimensional structure was a major challenge in 1980 when the inventions in this case were made, as evidenced by Sugano's failure to do so. JA05194-205.

i. Knowledge of the Genetic Code Did Not Enable Production of a Functional Protein

In holding the Fiers claims to be patentably indistinct from the DNA claims of the '096 interference, the PTAB relied in part on "the known genetic code indicating which DNA sequences encode each amino acid." JA02808. However,

“the known genetic code” upon which the PTAB relied is simply the set of rules for translating the sequence of nucleotide triplets of DNA (or RNA) into the primary amino acid sequence of the protein for which the DNA (or RNA) codes. *See In re O’Farrell*, 853 F.2d at 896-99. But the primary amino acid sequence is not the functional protein. It is simply a formula. This Court’s predecessor has held that, “a formula is not a compound and while it may serve in a claim to identify what is being patented, as the metes and bounds of a deed identify a plot of land, the thing that is patented is not the formula, but the compound identified by it” *In re Papesch*, 315 F.2d 381, 391 (CCPA 1963). Fiers does not seek to patent the mere amino acid sequence of the hFIF protein, but rather the functional protein. That protein is distinct – both functionally and patentably – from a nucleic acid sequence that encodes it.

ii. Producing a Functional Protein Was a Major Challenge in 1980

Previous PTAB decisions have commented on the difficulty of producing a functional recombinant protein in the time frame of the Sugano JP priority application and the Fiers ‘306 GB application:

[A]s of April 1980, the ability of workers to express human proteins in bacteria was a very recent advance in molecular biology, i.e., the field was in its infancy. At that time, researchers were not directly expressing heterologous genes in bacteria in a routine manner...researchers in the art of molecular biology were seriously concerned that attempts to produce specific mature mammalian proteins in bacteria would be fraught with problems since bacteria

simply do not ordinarily produce mammalian or other eukaryotic proteins and there are major differences that render efforts to express specific mammalian proteins in bacteria unpredictable.

Goeddel v. Wiseman, Interference No. 101,601, 1995 Pat. App. LEXIS 10 at *29 (BPAI). Fiers should be entitled to introduce evidence in the '939 interference to demonstrate that in 1980 mere possession of the DNA sequence fell far short of possession of the functional protein required by the claims. Human FIF proteins are very different from the DNA encoding such proteins. The hFIF protein is the biologically active component that exerts an effect, e.g., an antiviral effect or an effect on multiple sclerosis, whereas the DNA encoding hFIF provides a template used by cellular components for translating the DNA sequence into an amino acid sequence. DNA consists of a sequence of deoxyribonucleotides, whereas a functional protein consists of a string of amino acids bound together by peptide bonds and folded into a complex and critical three-dimensional shape (often containing intramolecular disulfide bonds). Thus DNA and proteins are very different chemical compounds. In 1980, the mere fact that a skilled scientist could write down the primary amino acid sequence of hFIF protein based on the genetic code and the hFIF DNA sequence fell far short of establishing that properly processed and biologically active protein was obvious over the DNA. The PTAB erred by resolving this important factual issue summarily on an order to show

cause. Moreover, the PTAB failed to cite to any evidence to support its conclusion.

3. The PTO Required the Protein Claims to be Restricted

The Board further erred in disregarding the restriction requirement imposed during the prosecution of the Fiers '609 application and concluding the subject matter of *that very* application rendered the '843 application obvious. JA00014. This conclusion is in direct contradiction of 35 U.S.C. §121 and alone warrants reversal.

During prosecution of the Fiers '609 application, the examiner issued a restriction requirement that forced Fiers to select between protein claims and DNA claims. JA04821-04825. Specifically, the examiner concluded that the Fiers '609 patent application contained “more than one invention,” including the DNA and protein claims. JA04823. Or put differently, the DNA and protein claims were patentably distinct.¹⁵ As a result, the '843 application at issue here (a divisional of the '609 application) was entitled to the benefits of 35 U.S.C. §121. That statute provides, in relevant part

¹⁵ This Court's predecessor articulated a test for the determination of whether two inventions are the same by noting, “[a] good test, and probably the only objective test, for ‘same invention,’ is whether one of the claims could be literally infringed without literally infringing the other. If it could be, the claims do not define identically the same invention.” *In re Vogel*, 422 F.2d 438, 441 (CCPA 1970). Because a DNA claim can be literally infringed without literal infringement of a protein claim, then the two inventions must not be the same.

A patent issuing on an application with respect to which a requirement for restriction under this section has been made, or on an application filed as a result of such a requirement, shall not be used as a reference either in the Patent and Trademark Office or in the courts against a divisional application or against the original application or any patent issued on either of them, if the divisional application is filed before the issuance of the patent on the other application.

By the plain language of the statute, the earlier Fiers application could not be prior art with respect to the '843 application.¹⁶ For this reason, this Court has characterized §121 as a “safe harbor” to protect a patent applicant from a situation in which the PTO requires an applicant to remove claims to inventions it deems patentably distinct, only for a later court to conclude that the inventions are not patentably distinct. *St. Jude Med., Inc., v. Access Closure, Inc.*, 729 F.3d 1369, 1376-77 (Fed. Cir. 2013).

The PTAB failed to explain why Fiers is not entitled to rely on the restriction requirement imposed by the PTO and benefit from the protection of §121. Instead, the PTAB relied on out-of-context quotations to conclude that the restriction requirements “are ‘matters of a mere discretionary, procedural or nonsubstantive nature.’” JA00014-15. Specifically, the PTAB cites to *Applied*

¹⁶ Although the PTAB did not explicitly state that it was applying the earlier Fiers DNA claims “as a reference” against the restricted out protein claims, that is the inevitable effect of its ruling. The earlier Fiers (and Sugano) DNA claims were the basis for the DNA Counts of the earlier interferences. By holding the current protein claims to be obvious - not patentably distinct - over those earlier DNA claims, the PTAB is necessarily using those DNA claims as a reference.

Materials, Inc. v. Advanced Semiconductor Materials Am., Inc., 98 F.3d 1563, 1568-69 (Fed. Cir. 1996). However, in that case, the Court was explaining that § 121 was specifically designed to protect patents resulting from restriction requirements from being “held invalid over the other merely because of their being divided in several patents.” Likewise, the PTAB cites to Judge Newman’s dissent in *Bristol-Myers Squibb Co. v. Pharmachemie B.V.*, 361 F.3d 1343, 1352 (Fed. Cir. 2004) which criticizes the majority for what the dissent characterizes as an overly strict reading of §121 in the context of a complicated prosecution history. Both decisions, when read in context, stand for the proposition that §121 protects patentees who properly file divisional applications in response to restriction requirements – as Fiers did here. But the PTAB simply dismissed the import of the restriction requirement, and so denied Fiers the safe harbor protection of §121.

The PTAB’s decision also violates the policy behind §121 of shielding an applicant who complies with the PTO’s rules.¹⁷ The PTO cannot, in equity, take a course of action that penalizes Fiers’ compliance with the examiner’s restriction requirement during prosecution of the Fiers ’609 application. The PTAB’s

¹⁷ Fiers relied on the determination of the examiner, and proceeded as required under §121. Fiers should not now be required to prove that the decision of the examiner was correct. *Studiengesellschaft Kohle v. N. Petrochemical Co.*, 784 F.2d 351, 361 (Fed. Cir. 1986) (Newman, J. concurring) (“section 121 effects a form of estoppel that shields the applicant from having to prove the correctness of the restriction requirement in order to preserve the validity of the second patent”).

decision is fundamentally unfair to Fiers in this respect, and law and equity compel a conclusion that the PTAB's decision was incorrect. *In re Kroekel*, 803 F.2d at 709 (interference estoppel "should be decided on the facts of each case with reference to principles of equity")

4. The PTO Has Previously Determined Protein and DNA are Patentably Distinct

The PTO's prior actions support a finding that claims to DNA encoding hFIF and claims to the hFIF protein itself are patentably distinct. For example, (1) the BPAI declared two separate interferences between Sugano and Goeddel to determine priority between DNA and protein claims, (2) the BPAI previously found the Sugano '859 and '567 patents (claiming DNA) do not anticipate the Fiers protein claims, and (3) the PTO has not required a terminal disclaimer in the Sugano '757 application in view of the Sugano '859 and '567 patents.

i. The BPAI Previously Recognized the Patentable Distinctness of hFIF DNA and Protein Claims by Declaring Separate Interferences Between Sugano and Goeddel

The BPAI declared the '334 interference (DNA) and the '337 interference (protein) to determine priority of invention between Sugano and Goeddel with respect to hFIF. JA05053-59, JA05060-65. The PTAB conveniently dismisses this holding as irrelevant, stating that "the discretionary decision to declare an interference is not necessarily indicative of whether individual interferences

concern separately patentable subject matter.” JA00015. But the PTAB’s dismissal of this argument is belied by the rules governing interferences.

An interference Count defines the subject matter of a particular interference. Under the pertinent regulations, a claim corresponds to a count if the subject matter of the Count, treated as prior art to the claim, would have anticipated or rendered obvious the subject matter of the claim. 37 CFR §41.207(b)(2). Thus, according to the PTAB’s own rules, the declaration of two separate interferences meant the protein claims in the Sugano and Goedell interferences were patentably distinct from the DNA claims. The same principle should apply to Fiers.

ii. The BPAI Has Previously Found that the Sugano DNA Claims Do Not Anticipate Fiers’ Protein Claims

Similarly, the BPAI has also reversed an Examiner’s rejection of the same Fiers claims involved in the ’939 interference over the DNA claims in the Sugano ’859 and ’567 patents. The Examiner rejected the Fiers protein claims as anticipated by the claims of the Sugano DNA patents, because the Sugano patents disclosed a DNA that encodes the same amino acid sequence as that recited in the Fiers claims. The BPAI reversed the examiner’s rejection because “[t]he Examiner has not established an evidentiary basis on this record to support a conclusion that the Appellant’s claimed recombinant polypeptide, composition, and method are patentably indistinguishable over the subject matter of [the ’096 interference] count or the DNA claims involved in the *Fiers v. Revel* interference.” JA005206-

5213 at 12. Thus, the BPAI determined there was not sufficient evidence on the record to make a determination as to whether the protein claims are patentably distinguishable from the DNA claims.¹⁸ In doing so, the BPAI acknowledged that the protein and DNA claims may be patentably distinct – otherwise it would have simply affirmed the Examiner. It is also noteworthy that the BPAI’s reversal was based on a lack of evidence, which is explicit recognition that questions of fact regarding the patentable distinctness of DNA and protein claims exist. For this reason alone, the ’939 interference should proceed, so that Fiers has an opportunity to establish an evidentiary record upon which an appropriate decision can be based.

iii. The PTO Did Not Require Sugano to Submit a Terminal Disclaimer of Protein Claims, Despite Sugano’s Issued DNA Claims

Finally, if the PTO had considered the protein claims of Sugano’s involved ’757 application (claiming protein) to be patentably indistinct from the claims in Sugano’s involved ’859 and ’567 patents (claiming DNA), then the PTO would have required a terminal disclaimer over those patents in the ’757 application. But no such terminal disclaimer was required by the PTO. That the PTO did not require a terminal disclaimer in this instance is entirely consistent with the fact that

¹⁸ As noted above, the PTAB’s Decision suffers from this same lack of evidence, and so should also be reversed for this same reason.

the PTO has routinely considered claims to DNA encoding hFIF to be separately patentable from the claims to the hFIF proteins.

Fiers has never been permitted to contest the priority of the protein claims, and should not be estopped from doing so in the '939 interference. Fiers should at least be afforded the same opportunity to separately contest these issues as Goeddel. The PTAB cannot be permitted to reverse its previous determination that the claims are patentably distinct, particularly with no actual evidence or explanation as to why the earlier determination was incorrect, and subject Fiers to a different standard. It is unfair and inequitable to Fiers for the PTAB to reverse its position on this critical point.

C. Interference Estoppel Should Not Apply Because Fiers Attempted to Add a Count to the Protein Claims in the '096 Interference

Fiers should not be estopped from pursuing its claims because the PTAB erred as a matter of law in concluding that the protein claims were not patentably distinct from the DNA claims on the record before it. But, in addition, estoppel does not apply where a party was precluded from raising an issue. *See Stoudt v. Guggenheim*, 651 F.2d 760, 764 (CCPA 1981) (“Guggenheim offers no authority whatsoever for the proposition that estoppel applies where a party has attempted to add a count and has been rebuffed. Indeed the authority is the other way.”). This is precisely what occurred here.

The PTAB's decision states that the dismissal of Fiers' motion to add an additional Count to the '096 interference was evidence supporting interference estoppel. JA00016-17. However, the PTAB's characterization of the pertinent events in the '096 interference is misleading. During the pendency of the '096 interference, Fiers moved to add a count directed to the hFIF protein. JA04868. The BPAI denied Fiers' motion. JA04886-91. The rules in effect at the time of the '096 interference required a party who proposed an additional count to show why the count was patentable to the other party.¹⁹ 37 C.F.R. §1.231(a)(2) (1982). But Fiers could not make such a showing, because Fiers did not believe the protein counts were supported by the Sugano specification. Indeed, Fiers clearly stated that the protein count was not patentable to Sugano, and invited Sugano to explain how the Sugano specification supported a protein count. JA04879-81. Tellingly, Sugano declined this invitation, and opposed the Fiers motion only on the procedural ground that Fiers had not explained why the protein count was supported by the Sugano specification. JA05214-15. The BPAI ultimately denied Fiers' motion to add the proposed protein count, because of Fiers' failure to show that the protein claims were supported by the Sugano specification. JA04886-91.

¹⁹ The rules have changed since the '096 interference was pending, and a party seeking to add a Count in an interference no longer needs to demonstrate why the Count is patentable to the other party. Thus, the situation facing Fiers in the 1980s no longer exists.

Fiers, in good faith, did everything possible to have the subject matter of the protein count resolved in the '096 interference. Fiers could not have complied with the BPAI rule to demonstrate that the protein count was supported by the Sugano application, because Fiers did not then – and does not now – believe that to be true. Notably, this Court has already determined that the Sugano application does not support claims to the mature protein count. *Goeddel*, 617 F.3d at 1357. For Fiers to have asserted otherwise would have been contrary to its duty of candor and a violation of the ethical rules governing attorneys practicing before the PTO. Nonetheless, Fiers did everything possible to raise the issue, thus giving Sugano and the BPAI an opportunity to expand the interference to include the hFIF protein invention. To find now that the consequence of Fiers' motion to add a proposed count is to result in interference estoppel is an unjust and inequitable result.

IV. The PTAB's Decision Is in Error Because Fiers Can Prevail on Priority

A. Legal Standard for Response to an Order to Show Cause

The Board issued an Order to Show Cause with respect to the issue of interference estoppel under Rule 202 (d). JA02806-09; *see* 37 C.F.R. §41.202. The burden placed on a party responding to an order to show cause “is not to prove beyond a reasonable doubt, or even by a preponderance of the evidence, but merely to establish a prima facie case.” *Schwab v. Pittman*, 451 F.2d 637, 640 (CCPA 1971). To establish a prima facie case such that a party is entitled to proceed with

an interference, the party is only required to prove by way of affidavits setting forth facts that would entitle it “to an award of priority if the senior party were to rely only on its filing date and were not to rebut any of the junior party’s case.”

Hahn v. Wong, 892 F.2d 1028, 1032 (Fed. Cir. 1989). It is further assumed that the allegations set forth in a party’s affidavit evidence are true. *Kahl v. Scoville*, 609 F.2d 991, 995 (CCPA 1979).

B. Fiers Can Prevail on Priority

1. This Court Has Determined That the Sugano JP Priority Application Lacks Support for the Mature Protein Claims

The Order was, separately and independently, in error because Sugano cannot claim priority of invention at least with respect to Count 1. Sugano has previously litigated, and lost in *this Court*, the question of whether the Sugano priority application provided written description support for the mature protein claims. The well-established principles of issue preclusion bar Sugano from re-litigating that question in the current litigation. *See, e.g., Comair Rotron, Inc. v. Nippon Densan Corp.*, 49 F.3d 1535, 1537 (Fed. Cir. 1995).

In the ’939 interference, Sugano was accorded the benefit of the Sugano JP priority application, filed March 19, 1980, and Fiers was awarded the benefit of the Fiers ’306 GB application, filed April 3, 1980. JA00190-91. On the basis of these dates, Sugano was designated the Senior Party. JA00188. But this Court has held that the Sugano JP priority application lacks written descriptive support for the

mature protein claims involved in Count 1 of the '939 interference. *Goeddel*, 617 F.3d at 1357. Sugano has conceded this fact. *Id.* at 1355. Thus Sugano lacks support for at least the protein encompassed by Count 1, and is not Senior Party with respect at least to Count 1. That holding is binding here. *See, e.g., Dana Corp. v. NOK, Inc.*, 882 F.2d 505, 506-07 (Fed. Cir. 1989) (applying collateral estoppel to the best mode requirement of section 112). Fiers should instead be designated Senior Party with respect to Count 1, and so should not be subject to an Order to Show Cause.

2. The Sugano JP Priority Application Lacks Support for Expressing Proteins

The Sugano JP priority application lacks support for both of the interference Counts. Fiers has submitted evidence in the '939 interference that demonstrates that the Sugano JP priority application does not disclose a single enabled embodiment for producing an hFIF protein. Fiers' expert, David A. Jackson, Ph.D., submitted a declaration in response to the Order showing that the Sugano JP priority application neither describes nor enables functional hFIF proteins. JA05194-05205. For example, at paragraphs 22-25 of his declaration, Dr. Jackson explains that:

22. It is my opinion that Sugano's March 1980 Japanese (Exhibit 2011) (the "Sugano application") in the interference fails to sufficiently disclose a human fibroblast interferon of either Count 1 or Count 2, and/or how to make such a protein.

23. Specifically, the Sugano March 1980 Japanese application (Exhibit 2011) fails to disclose even a single enabled embodiment for producing an hFIF protein.

24. The Sugano application (Exhibit 2011) only describes the means for producing the DNA encoding immature hFIF in *E. coli* (i.e., only cloning vectors, not expression vectors). Sugano does not describe any means for expressing proteins, much less for expressing them in mammalian cells which is required for correct glycosylation to occur.

25. The Sugano application (Exhibit 2011) does not even assert that systems for the expression of human fibroblast interferon or any proteins are known and available in the art.

JA05201. Dr. Jackson proceeds to explain the bases for his opinions that, as of early 1980, the Sugano JP priority application provided neither descriptive nor enablement support for the claims to hFIF proteins. The Sugano JP priority application does not describe any method for expressing proteins, much less for expressing proteins in mammalian cells. For example, the Sugano JP Priority application provides no starting materials, vectors, control sequences for gene expression, methods for detecting expression or any other details that would be required for producing proteins. The Sugano JP priority applications fails even to point to any prior art procedures or cite to any references that would be enabling for the expression of hFIF proteins.

There is simply no evidence that the Sugano applicants understood the complexity of producing the hFIF protein, much less a functional hFIF protein that is capable of displaying antiviral activity. After cloning hFIF DNA and after filing the Sugano JP priority application, the Sugano applicants entered a collaboration

with one of the leading molecular biology laboratories in the world – that of Dr. Mark Ptashne at Harvard University – to achieve expression of hFIF protein. The Ptashne laboratory claimed to possess advanced systems for the expression of proteins. JA05237-364 at 250, 254. Enablement and written description must be met at the time of filing. *See, e.g., Enzo Biochem, Inc. v. Calgene, Inc.*, 188 F.3d 1362, 1371-72 (Fed. Cir. 1999); *Moba, B.V. v. Diamond Automation, Inc.*, 325 F.3d 1306, 1319 (Fed. Cir. 2003). The evidence shows that the Sugano JP priority application neither described nor enabled the expression of functional hFIF protein.

Nor can Sugano claim the Sugano JP priority application is enabled solely by asserting that a method for expression of the proteins was known in the prior art. *Genentech, Inc. v. Novo Nordisk A/S*, 108 F.3d 1361, 1366 (Fed. Cir. 1997) (explaining that when there is no disclosure of specific starting material or conditions for carrying out a process, the enablement requirement cannot be met by asserting a person of skill in the art could have carried out the process).

Accordingly, the Sugano JP priority application does not describe or enable the subject matter of either Count 1 or Count 2, and so Sugano should not be accorded the benefit date of that application. In the absence of such benefit, Fiers is properly the Senior Party.

3. The Fiers '306 GB Application Describes Protein Expression

In contrast to the dearth of protein information in the Sugano JP priority application, the Fiers '306 GB application describes in great detail the process for expressing proteins, and specifically the expression of hFIF. JA04653-721. The Fiers '306 GB application is a very thorough and considered document that a person of ordinary skill could, with the information disclosed and the scientific publications cited, take into the laboratory and express hFIF in both its mature and precursor forms with a reasonable chance of success. For example, the Fiers specification refers to the use of “expression control sequences,” useful plasmids, useful hosts, transformation of hosts to produce protein, and expression characteristics to be considered. JA04671-72, JA04679-83, JA05202-03. As a result, the Fiers '306 GB application fully describes and enables the subject matter of the '939 interference Counts. For at least these reasons, Fiers has demonstrated that it would prevail in the '939 interference, and should be permitted to proceed.

CONCLUSION

For the reasons discussed above, the District Court's conclusion that it lacks subject matter jurisdiction is legally erroneous and this Court should vacate the District Court's transfer order and remand for further proceedings under §146. However, if this Court affirms the District Court's determination, and subsequently addresses the PTAB's decision in the underlying interference, then for the

additional reasons discussed above this Court should reverse the PTAB's decision that interference estoppel applies to Fiers and should remand for further proceedings at the PTAB.

Dated: August 4, 2014

Respectfully submitted,

/s/ E. Anthony Figg

E. Anthony Figg

R. Danny Huntington

Daniel R. McCallum

ROTHWELL, FIGG, ERNST &
MANBECK, P.C.

ADDENDUM 1

Memorandum & Order on Motions to Dismiss - May 22, 2014 (Mass.)
(Docket No. 55)

JA00001 - JA00012

2014-1525
Biogen Idec MA, Inc.

v.

Japanese Foundation for Cancer Research and Bayer Pharma AG

**UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS**

BIOGEN IDEC MA, INC.,

Plaintiff,

V.

**JAPANESE FOUNDATION FOR CANCER
RESEARCH and BAYER PHARMA AG,**

Defendants.

Civil No.
13-13061-FDS

**MEMORANDUM AND ORDER ON
MOTIONS TO DISMISS**

SAYLOR, J.

This claim arises out of a decision of the United States Patent and Trademark Office (“PTO”) Patent Trial and Appeal Board (“PTAB”). On July 16, 2013, the PTO declared an interference between various claims of U.S. Patent Application No. 08/253,843 (currently owned by Biogen Idec MA, Inc.) and U.S. Patent Application No. 08/463,757 (currently owned by Japanese Foundation for Cancer Research and licensed to Bayer Pharma AG). On October 3, 2013, the PTAB found that the outcome of prior interference proceedings estopped the assertion of the claims of the ‘843 application and finally refused those claims. Dissatisfied with the PTAB’s decision, Biogen Idec sought review by this Court pursuant to 35 U.S.C. § 146 and 28 U.S.C. §§ 1331 and 1338(a).

Defendants have moved to dismiss the claim for lack of personal and subject-matter jurisdiction. For the reasons set forth below, this Court lacks subject-matter jurisdiction and will therefore transfer the action to the United States Court of Appeals for the Federal Circuit.

I. Background

The underlying dispute concerns human fibroblast interferon (“hFIF”), a human protein that possesses useful antiviral and immunological effects and is employed, among other things, to treat multiple sclerosis. The ‘843 and ‘757 applications both contain claims involving hFIF proteins.

In the United States, only one patent is permitted for any given patentable invention. For most of its history, the American patent system granted patents to the first person to invent the patentable invention. If multiple parties claiming the same invention disputed which first invented it, there were procedures to determine which one was entitled to the patent. Such procedures include interference proceedings before the Board of Patent Appeals and Interferences (“BPAI”).

In 2011, Congress passed the Leahy-Smith America Invents Act (“AIA”), Pub. L. No. 112-29, 125 Stat. 284 (2011), converting the patent system from “first-to-invent” to “first-inventor-to-file.” Under the new framework, if multiple parties claim the same invention, the first party to file a patent application generally is entitled to the patent. Of course, many patents issued under the old, first-to-invent framework remain in effect and may be subject to dispute. The issue here arises out of the transition from the old system to the new.

A. Prior Statutory Framework

Under the old system, the Director of the PTO was authorized to declare an interference between different patents or patent applications when they appeared to claim the same invention. 35 U.S.C. § 135 (2006). The BPAI would then conduct a proceeding to determine priority of invention and patentability. *Id.* Once the BPAI rendered a final decision, an aggrieved party

could either seek review in the Court of Appeals for the Federal Circuit, 35 U.S.C. § 141 (2006), or in a district court that had personal jurisdiction over the winning interferent, *id.* § 146.

B. Current Statutory Framework

On September 16, 2011, the AIA became law. It instituted a phased implementation of the Act's provisions, with most changes going into effect on September 16, 2012, or March 16, 2013 (that is, twelve or eighteen months after enactment).

Interference proceedings have been abolished. Instead, under the new § 135, the Director of the PTO may institute a derivation proceeding to determine whether the first-filing inventor derived (essentially, misappropriated) the claimed invention from a later-filing inventor. 35 U.S.C. § 135(a), (b). Those proceedings are heard by the PTAB, which has replaced the BPAI. 35 U.S.C. § 6; *see* AIA § 3(j)(1). Applicants who are dissatisfied with the final decision of the PTAB in a derivation may seek review in the Federal Circuit, 35 U.S.C. § 141, or in the District Court for the Eastern District of Virginia, *id.* § 146.

C. Procedural Background

On June 3, 1994, Walter C. Fiers filed the '843 patent application, which Biogen Idec now owns.¹ The '843 application was a division of an earlier patent application by Fiers, no. 07/387,503, filed July 28, 1989, which was a division of patent application no. 06/250,609, filed April 3, 1981. On June 5, 1995, Haruo Sugano, Masami Muramatsu, and Tadatsugu Taniguchi filed the '757 patent application, which JFCR now owns. The '757 application claims priority to patent application no. 06/201,359, which also was filed by Sugano.

On August 30, 1983, the PTO declared an interference (no. 101,096) between the '609

¹ The facts in this subsection are presented as stated in the complaint.

and ‘359 applications concerning hFIF DNA. The BPAI awarded priority to the Sugano ‘359 application. That finding was upheld on appeal. *Fiers v. Revel*, 984 F.2d 1164 (Fed. Cir. 1993).

On July 16, 2013, the PTO declared an interference (no. 105,939) between the ‘843 and ‘757 applications, which both contain claims to hFIF. At the same time, the PTO issued an Order to Show Cause to Fiers to show why judgment should not be entered against him based on interference estoppel and issue preclusion from the earlier ‘096 interference. Fiers responded to the Order, as did Sugano. Fiers also filed a paper presenting the issues of his intended motions in the interference proceeding, which included obviousness, written description, enablement, and priority.

On October 3, 2013, the PTAB found that because of the ‘096 interference, Fiers was estopped from asserting the claims in the ‘843 application. The PTAB entered judgment against Fiers and ordered that the claims in the ‘843 application be finally refused.

On December 2, 2013, Biogen Idec filed suit in this Court against JFCR and against the interested parties whom JFCR had listed in the interference: Bayer Pharma AG, Kyowa Hakko Kirin Co., Ltd., and Toray Industries, Inc. On March 28, 2014, JFCR and Bayer moved to dismiss the complaint for lack of personal and subject-matter jurisdiction under Fed. R. Civ. P. 12(b)(1), 12(b)(2), and 12(b)(6). On April 2, 2014, the Court dismissed without prejudice all claims against Kyowa and Toray pursuant to the parties’ agreement that they were not indispensable parties.

II. Standard of Review

Federal courts are courts of limited jurisdiction. They possess only those powers granted by either the Constitution or statute, and cannot adjudicate claims absent such power. *See, e.g.,*

Kokkonen v. Guardian Life Ins. Co. of Am., 511 U.S. 375, 377 (1994). Accordingly, the existence of subject-matter jurisdiction is never presumed. *Fafel v. DiPaola*, 399 F.3d 403, 410 (1st Cir. 2005). Instead, “the party invoking the jurisdiction of a federal court carries the burden of proving its existence.” *Murphy v. United States*, 45 F.3d 520, 522 (1st Cir. 1995).

In ruling on a motion brought under Fed. R. Civ. P. 12(b)(1), the court must credit the well-pleaded factual allegations of the complaint and draw all reasonable inferences in the plaintiff’s favor. *Merlonghi v. United States*, 620 F.3d 50, 54 (1st Cir. 2010). The court may also consider other evidence, including depositions and exhibits submitted by either party. *Id.*

III. Analysis

The basic issue presented is whether an aggrieved party to an interference declared after September 16, 2012, has a right to appeal to federal district court, or whether the only remedy is an appeal to the Federal Circuit. More precisely, the question is whether any provision in the law affirmatively grants subject-matter jurisdiction to this Court to hear this dispute.² The answer to that question requires interpretation of two statutes: the AIA and the AIA Technical Corrections Act, Pub. L. No. 112-274, 126 Stat. 2456 (2013).

In matters of statutory construction, the proper starting point is the language of the statute itself. *See Watt v. Alaska*, 451 U.S. 259, 265 (1981). Section 3 of the AIA generally institutes the first-inventor-to-file system. *See* AIA § 3(o), (p), 125 Stat. 293 (expressing the sense of Congress about the benefits of a first-inventor-to-file system). Among other changes, it sets

² Plaintiff, at times, frames the question as one of stripping jurisdiction from the district court. (*See* Pl. Mem. at 12). While it is true that district courts had jurisdiction over interference appeals under pre-AIA § 146 and only the Eastern District of Virginia has jurisdiction under post-AIA § 146, it is misleading to focus on the withdrawal of jurisdiction. The concept of limited federal-court power requires that a statutory provision affirmatively grant jurisdiction to this Court. *See Chase Manhattan Bank (Nat. Ass’n) v. S. Acres Dev. Co.*, 434 U.S. 236, 240 (1978).

conditions for patentability, creates new definitions, and imposes a new statute of limitations.

Section 3(i) replaced wholesale 35 U.S.C. § 135, so that there are derivation proceedings rather than interference proceedings. Section 3(j) then eliminated references to interferences in existing law by, among other things, “striking ‘Board of Patent Appeals and Interferences’ each place it appears and inserting ‘Patent Trial and Appeals Board’” in 35 U.S.C. §§ 134, 145, 146, 154, and 305 and by striking “interference” and inserting “derivation” in 35 U.S.C. § 146.

AIA § 3(n) established the effective date for the changes made by § 3. It provides:

(1) In general.—Except as otherwise provided in this section, the amendments made by this section *shall take effect upon the expiration of the 18-month period beginning on the date of the enactment of this Act, and shall apply to any application for patent, and to any patent issuing thereon, that contains or contained at any time—*

(A) a claim to a claimed invention that has an effective filing date as defined in section 100(i) of title 35, United States Code, that is on or after the effective date described in this paragraph; or

(B) a specific reference under section 120, 121, or 365(c) of title 35, United States Code, to any patent or application that contains or contained at any time such a claim.

(2) Interfering patents.—The provisions of sections 102(g), 135 [interferences], and 291 of title 35, United States Code, as in effect on the day before the effective date set forth in paragraph (1) of this subsection, shall apply to each claim of an application for patent, and any patent issued thereon, for which the amendments made by this section also apply, if such application or patent contains or contained at any time—

(A) a claim to an invention having an effective filing date as defined in section 100(i) of title 35, United States Code, that occurs before the effective date set forth in paragraph (1) of this subsection; or

(B) a specific reference under section 120, 121, or 365(c) of title 35, United States Code, to any patent or application that contains or contained at any time such a claim.

AIA § 3(n) (emphasis added). For present purposes, this provision divides patents into two

categories: (1) those with claims filed after March 16, 2013, and (2) those with claims filed before March 16, 2013. Patents in the first category (“post-AIA patents”) are subject to the new first-inventor-to-file system, as set forth in § 3. For patents in the second category (“pre-AIA patents”), the pre-AIA versions of certain sections continue to apply. Former § 135, relating to interference proceedings, generally applies to disputes involving pre-AIA patents.

The parties disagree as to the meaning of AIA § 3(n)(1). Plaintiff contends that because the provision states that “the amendments made by this section . . . shall apply to any” post-AIA patent, the logical inference is that the law as it existed prior to those amendments continues to apply to any pre-AIA patents—including pre-AIA § 146, which provides for an appeal from interference decisions in the district courts. Defendants argue that while the amendments creating a first-to-file system apply to post-AIA patents, the amendments went into effect across the board, sweeping away the old versions of the law except as specifically provided in the AIA.

The latter view appears to be the correct interpretation. The AIA specifically provides which sections of prior law will still apply: §§ 102(g), 135, and 291. AIA § 3(n)(2). The logical inference, therefore, is that the sections that are not specifically mentioned continue to exist—if at all—only as amended after March 16, 2013. *Cf. Cipollone v. Liggett Group, Inc.*, 505 U.S. 504, 517 (1992) (applying the principle of “*expressio unius est exclusio alterius*”). Thus, the changes to § 146—substituting “derivation” for “interference” and the PTAB for the BPAI—were in effect at the time that the Director declared the ‘939 interference.

That is not, however, the end of the inquiry. While AIA § 3 as enacted provided, to a limited extent, for parallel systems for pre- and post-AIA patents, it also left a gap. AIA § 3(n)(2) provided that interferences under the pre-AIA § 135 would continue, but there no longer

was a BPAI to adjudicate the dispute and no route of appeal. AIA § 6 partially filled that gap, but only for interferences commenced before September 16, 2012 (“pending interferences”). AIA § 6(f)(3) provides that Director of the PTO should determine whether pending interferences should be dismissed without prejudice or “proceed as if this Act had not been enacted” and may “deem” the PTAB to be the BPAI. AIA § 6(f)(3)(A), (B). Subsection 6(f)(3) further states as follows:

The authorization to appeal or have remedy from derivation proceedings in section 141(d) [to the Federal Circuit] and 146 [to the Eastern District of Virginia] of title 35, United States Code, as amended by this Act, and the jurisdiction to entertain appeals from derivation proceedings in section 1295(a)(4)(A) of title 28, United States Code, as amended by this Act, shall be deemed to extend to any final decision in an interference that is commenced before [September 16, 2012] and that is not dismissed pursuant to this paragraph.

AIA § 6(f)(3)(C). Thus, interferences commenced before September 16, 2012, had a venue at the PTAB and a right to appeal to the Federal Circuit or the Eastern District of Virginia as if they were derivation proceedings.³ But the law as originally enacted made no mention of venue or appeal from interferences commenced *after* September 16, 2012—even though AIA § 3 clearly contemplated that such proceedings would be allowed.⁴

³ AIA § 7 established the PTAB to review adverse decisions of examiners, review appeals of reexaminations, conduct derivation proceedings, and conduct *inter partes* reviews and post-grant reviews. Appeals of PTAB decisions are to the Federal Circuit and, for derivation proceedings, also to the Eastern District of Virginia, where the PTO is located. AIA § 7(c); see Joe Matal, *A Guide to the Legislative History of the America Invents Act: Part II of II*, 21 Fed. Circuit B.J. 539, 624 (2012) (explaining the change in venue to the Eastern District of Virginia). Section 7 went into effect on September 16, 2012, and generally applies to all proceedings commenced after that date. *Id.* § 7(e).

⁴ Plaintiff points to a statement by Senator Kyl to support its argument that Congress intended for pre-AIA §§ 141 and 146 to apply to all remaining interferences. For at least two reasons, that argument is unpersuasive. The senator stated that

To address the continuing need to allow appeals of pending interferences, language has been added to Section [6(f)(3)(C)] of the bill that deems references to derivation proceedings in the current appeals statutes to extend to interferences commenced before the effective date of the bill’s repeal of interferences, and that allows the Director to deem the PTAB to be the BPAI for

Congress then enacted the AIA Technical Corrections Act (“TCA”), which became law on January 14, 2013. Section 1(k)(3) of the TCA addresses review of interference proceedings:

The provisions of sections 6 [establishing the BPAI] and 141 [providing review at the Federal Circuit] of title 35, United States Code, and section 1295(a)(4)(A) [providing Federal Circuit jurisdiction over interference appeals] of title 28, United States Code, as in effect on September 15, 2012, shall apply to interference proceedings that are declared after September 15, 2012, under section 135 [interferences] of title 35, United States Code, as in effect before [March 16, 2013]. The [PTAB] may be deemed to be the [BPAI] for purposes of such interference proceedings.

TCA § 1(k)(3). The TCA thus clearly provides that as to interferences declared after September 15, 2012—such as the one at issue here, which was declared on July 16, 2013—the PTAB may hear the dispute and there is a right of appeal to the Federal Circuit.

Plaintiff, however, argues that there remains a right of review in this Court. To be sure, the prior version of § 141 refers to § 146, which formerly provided for appeal of interference decisions in federal district court (and currently provides for appeal of derivation decisions to the Eastern District of Virginia). But the fact that the prior version of § 141 still exists for purposes of new interferences does not mandate that each section to which it refers also survives as it then existed. Congress demonstrated in AIA § 6(f)(3)(C) that it knew how to preserve both avenues of review. Instead, Congress chose in the TCA to reinstate pre-AIA § 141 appeals but to omit

purposes of pending interferences and to allow the PTAB to conduct such interferences.

157 Cong. Rec. S1360-02 (daily ed. March 8, 2011) (statement of Sen. Jon Kyl). First, the statement, like AIA § 6(f)(3)(C), addresses only interferences commenced before the Act goes into effect. It therefore does not speak to interferences, like the ‘939 interference, that were commenced later. Contrary to plaintiff’s contention, the “effective date of the bill’s repeal of interference” has passed, despite the fact that interferences may still be declared. Second, a statement by a senator, even directly on point, cannot override the plain language of a statute. *See Burlington N. R. Co. v. Oklahoma Tax Comm’n*, 481 U.S. 454, 461 (1987) (“Legislative history can be a legitimate guide to a statutory purpose obscured by ambiguity, but in the absence of a clearly expressed legislative intention to the contrary, the language of the statute itself must ordinarily be regarded as conclusive.” (internal quotations marks and citations omitted)).

pre-AIA § 146 appeals. Accordingly, the logical conclusion is that appeals of interferences declared on or after September 16, 2012, may be brought only in the Federal Circuit.

Plaintiff contends that the TCA did not explicitly reinstate § 146 because that section had never been eliminated. AIA § 3(n)(1), the argument goes, provides that the amendments apply only to post-AIA patents, and therefore the pre-AIA version of Title 35 lives on for pre-AIA patents. Not only would that be a highly unusual state of affairs, it also runs contrary to the plain language of the statute. Congress specifically identified which portions of the prior law continued and how they applied. Pre-AIA § 146 was preserved, but only for interferences that commenced before September 16, 2012.

The PTO regulations and commentary are not to the contrary. The newly enacted regulations governing judicial review of PTAB decisions state that “where available, judicial review of decisions arising out of interferences declared pursuant to 35 U.S.C. § 135 continue to be governed by pertinent regulations in effect on July 1, 2012.” 37 CFR § 90.1. The regulation does not say that judicial review *is* available, nor does it say *where* it is available. No inference can be drawn, as plaintiff contends, that judicial review of pre-AIA patent interferences is available in this Court. The comments underlying that proposed regulation state that “§ 3 of the [AIA] makes review of interference decisions by a district court under 35 U.S.C. 146 available only if the provisions of § 3(n)(1) . . . are not satisfied.” Patent & Trademark Office, Dep’t of Commerce, *Rules of Practice for Trials Before the Patent Trial & Appeal Board & Judicial Review of Patent Trial & Appeal Board Decisions*, 77 FR 6879, 6891 (Feb. 9, 2012). The comment continues: “To the extent that an interference proceeding under 35 U.S.C. [§] 135 is available and judicial review of that decision is available, the Office will continue to apply the

regulations as they existed when the [AIA] was enacted . . . to those proceedings.” *Id.* Again, the comment as a whole does not affirmatively state that judicial review *is* available, only that *if* it is, then certain regulations apply.⁵

Plaintiff also contends that because the PTO accepted its notice that it intended to appeal to district court rather than to the Federal Circuit, the law must permit appeals to district court. Whatever the meaning of the PTO’s acceptance may be, this Court, not the PTO, is charged with determining subject-matter jurisdiction in this proceeding.

In short, the PTAB declared the ‘939 interference on July 16, 2013, and the law as enacted by Congress permits an appeal only to the Federal Circuit. Accordingly, this Court is without subject-matter jurisdiction to review the PTAB’s decision.⁶

Plaintiff requested that in the event that this Court found that it lacks jurisdiction, rather than ordering dismissal, the Court transfer the action to the Federal Circuit. Under 28 U.S.C. § 1631, when a civil action or petition for review is filed in federal court and the court “finds that there is a want of jurisdiction, the court shall, if it is in the interest of justice, transfer such action or appeal to any other such court in which the action or appeal could have been brought at the time it was filed.” 28 U.S.C. § 1631; *see In re Teles AG Informationstechnologien*, 2014 WL 1327920 (Fed. Cir. Apr. 4, 2014) (holding that the district court that found it lacked jurisdiction erred in dismissing the case rather than transferring it). Accordingly, in the interest of justice, this Court will transfer the action to the Federal Circuit.

⁵ For example, judicial review under § 146 is available for interferences commenced prior to September 16, 2012, and the prior PTO regulations would apply to such proceedings.

⁶ Because it lacks subject-matter jurisdiction, the Court need not consider defendants’ alternate argument that it lacks personal jurisdiction over them.

ADDENDUM 2

Decision - Fiers Response to Order to Show Cause - October 3, 2013 - Paper 78
(PTAB)

JA00013 - JA00018

2014-1525
Biogen Idec MA, Inc.
v.
Japanese Foundation for Cancer Research and Bayer Pharma AG

BoxInterferences@uspto.gov
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Paper 78
Filed: 3 October 2013

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

WALTER C. **FIERS**
Junior Party
(Application 08/253,843),

v.

HARUO **SUGANO**, MASAMI MURAMATSU, and
TADATSUGU TANIGUCHI
Senior Party
(Application 08/463,757).

Patent Interference No. 105,939 (DK)
(Technology Center 1600)

DECISION
FIERS RESPONSE TO ORDER TO SHOW CAUSE

Before RICHARD E. SCHAFER, SALLY GARDNER LANE, and
DEBORAH KATZ, *Administrative Patent Judges*.
KATZ, *Administrative Patent Judge*.

An Order to Show Cause (“Order,” Paper 3) was entered against junior party
Fiers. The Order required Fiers to show why it would prevail on priority when it
had previously been unsuccessful. Fiers responded to the Order to Show Cause.

Interference 105,939

1 (“Response”, Paper 49.) Sugano filed an authorized opposition (“Opposition”,
2 Paper 64), and Fiers filed an authorized reply (“Reply”, Paper 69).

3 Judgment on the priority of invention was awarded to Sugano in prior
4 interferences 101,096 and 105,661 as to the precursor hFIF DNA sequence and the
5 mature hFIF DNA sequence, respectively. The Order to Show Cause was issued
6 based on the reasoning that because the protein sequences Fiers now claims would
7 have been obvious over the DNA sequences at issue in the prior interferences at
8 the time Fiers filed its priority application, Fiers is estopped from claiming this
9 subject matter. (*See* Order, Paper 3 at 3:18-20.) Fiers has not persuaded us
10 otherwise. Instead, Fiers acknowledges that in 1978 Dr. Fiers stated that amino
11 acid sequences can be deduced from nucleotide sequences. (*See* Reply, Paper 69 at
12 II-21, response to Sugano Statement of Material Facts 80 and 81.) Dr. Fiers’s
13 statement demonstrates the obviousness of proteins over the DNA that encodes
14 them.

15 Fiers argues that it is not estopped in the current interference because the
16 subject matter it now claims is patentably distinct from the subject matter it
17 previously claimed and lost. (Response, Paper 49, at 18:17-19:5.) As evidence,
18 Fiers points to requirements imposed during prosecution that restrict between
19 claims to DNA and claims to protein. (*Id.*, citing Material Facts 6 and 29, which
20 cite Exhs. 2014 and 2029.) This evidence is not persuasive of separate
21 patentability because restriction requirements are made for “examination
22 convenience,” not as a final determination on the subject matter claimed. *See*
23 *Applied Materials, Inc. v. Advanced Semiconductor Materials America, Inc.*, 98
24 F.3d 1563, 1568-69 (Fed. Cir. 1996) (explaining that that the validity of a patent
25 claim should not be questioned because of a restriction requirement was imposed
26 or not and that the “safe harbor” of 35 U.S.C. § 121 is “simply to safeguard patent
27 validity from the vagaries of the restriction practice, not to change the practice.”).

Interference 105,939

“Restriction requirements are like other PTO ‘requirements’ that are ‘matters of a discretionary, procedural or nonsubstantive nature.’” *Bristol-Myers Squibb Co. v. Pharmachemie B.V.*, 361 F.3d 1343, 1352 (Fed. Cir. 2004) (quoting *In re Henghold*, 440 F.2d 1395, 1403 (CCPA 1971)). Such discretionary, procedural decisions by the Examiner are not binding on the Board.

Fiers also points to the declaration of Interferences 105,334 and 105,337, between Sugano and party Goeddel, which each involved separate counts to corresponding DNA and protein. (Response, Paper 49 at 19:13-18.) Like the evidence of a restriction requirement, this evidence is not persuasive of separate patentability. The discretion to declare an interference does not preclude the Director from taking into account administrative concerns. *See* 35 U.S.C. § 135(a) (“Whenever an application is made for a patent which, in the opinion of the Director, would interfere with any pending application, or with any unexpired patent, an interference may be declared . . .”). Like the decision to impose a restriction requirement, the discretionary decision to declare an interference is not necessarily indicative of whether individual interferences concern separately patentable subject matter.

Fiers points to a Board decision in Appeal No. 2009-003064 as further evidence of separate patentability. (Response, Paper 49 at 18:22-19:4, citing Material Fact 30, which cites Exh. 2031.) Though the Board reversed the Examiner’s rejection of Fiers’s claims to hFIF protein over Sugano’s claims to hFIF DNA, it did not hold that there is *no* evidence that the Fiers protein claims were anticipated or obvious in view of the hFIF DNA. The Board only held that “the Examiner ha[d] not established an evidentiary basis on [the] record to support” such a conclusion. (Exh. 2031 at 6.) The Board’s decision does not establish that Fiers’s protein claims are patentably distinct from hFIF DNA. Indeed, the Board stated:

Interference 105,939

1 Given that the Examiner failed to meet his evidentiary burden, we
2 make no ruling as to whether the subject matter of the rejected claims
3 is patentably distinct from either (1) the subject matter of the count in
4 the *Fiers v. Revel* interference or (2) the claims that correspond to that
5 count.
6

7 (Exh. 2031 at 6.) Thus, the Board's decision is not determinative of whether Fiers
8 is now estopped from claiming the currently recited subject matter.

9 The Order to Show Cause indicates that the knowledge of those of skill in
10 the art regarding the genetic code would have rendered the polypeptides Fiers now
11 claims to have been obvious over the subject matter lost in the previous
12 interferences. (Order at 3:16-20; *see also* Opposition, Paper 64 at 9:1-19.) Fiers
13 does not contest this determination. Fiers presents the Declaration of David A.
14 Jackson, Ph.D. (Exh. 2030), but relies on it only to argue that the Sugano
15 March 1980 Japanese priority application does not provide an enabling description
16 of the proteins of the Counts. (Response, Paper 49 at 25:5-26:20.) Dr. Jackson's
17 testimony does not reach whether the proteins recited in the involved Fiers claims
18 would have been obvious over the subject matter Fiers lost in the prior
19 interferences.

20 Fiers also argues that it cannot be estopped from proceeding in the current
21 Interference because it attempted to add counts directed to the hFIF protein during
22 the prior 101,096 Interference and that motion was dismissed. (Response,
23 Paper 49 at 3:1-5 and 14:3-8.) As Fiers admits, the motion was dismissed because
24 it failed to adequately demonstrate the patentability of the proposed counts to the
25 parties, as required under then 37 C.F.R. §§ 1.231(a)(2) and 1.231(b). (*See*
26 Response, Paper 49 at 14:9-11 and Exh. 2019 at 5.) Fiers had an opportunity to
27 add counts to the hFIF protein, and exercised that opportunity, but failed to provide
28 an argument sufficient to win the relief sought. The prior dismissal of Fiers's

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1 motion to include counts directed to the hFIF protein is evidence *for* an estoppel
2 against Fiers, not evidence *against* one.

3 Fiers lost claims to the DNA encoding the precursor to hFIF in
4 Interference 101,096 and lost claims to the DNA encoding the mature hFIF in
5 Interference 105,661. This result is not changed by the Federal Circuit's holding in
6 Interferences 105,334 and 105,337. (*See* Response, Paper 49 at 20:6-22:12.) As
7 Fiers acknowledges it was not a party to those interferences. (Reply, Paper 69 at
8 3:8-9, and 7:16.) Fiers has not explained why the outcome of those interferences
9 should determine whether Fiers is estopped from claiming certain subject matter in
10 the present circumstances. Regardless of the benefit dates accorded to either Fiers
11 or Sugano, Fiers lost priority of the mature hFIF DNA to Sugano and Fiers is now
12 estopped from claiming subject matter not patentably distinct.

13 Whether Fiers could have raised enablement or other attacks on Sugano's
14 claims had the 105,661 Interference gone forward does not impact whether Fiers is
15 now estopped because Fiers did not request rehearing or raise an appeal of that
16 decision. The judgment against Fiers remains. Allowing Fiers to revisit the
17 decision in Interference 105,661 to argue that the mature DNA or protein is
18 unpatentable to Sugano would be "unfair to the winning party in the original
19 interference, and would be inconsistent with the general principle of *res judicata*
20 that a judgment should settle finally all issues that were decided or should have
21 been decided." *In re Deckler*, 977 F.2d 1449, 1451 (Fed. Cir. 1992).

22 Fiers argues that the issue of the first to invent the mature hFIF protein has
23 never been litigated between Fiers and Sugano (Response, Paper 49 at 22:10-12),
24 but the issue of first to invent subject matter patentably indistinct from the mature
25 hFIF protein has been previously litigated between Fiers and Sugano. Because
26 Fiers has failed to persuade us that the protein it currently claims would have been
27 unobvious over the DNA recited in the claims it previously lost, Fiers is estopped

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1 from claiming that protein. “[I]nterference estoppel [bars] the assertion of claims
2 for inventions that are patentably indistinct from those in an interference that the
3 applicant had lost.” *In re Deckler*, 977 F.2d at 1452.

4 Judgment against Fiers will be entered in a separate paper.

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ADDENDUM 3

Judgment - Bd.R. 127(a)(1) - October 3, 2013 - Paper 79 (PTAB)

JA00019 - JA00020

2014-1525
Biogen Idec MA, Inc.
v.
Japanese Foundation for Cancer Research and Bayer Pharma AG

Accordingly, it is **Ordered** that judgment be entered against Fiers in regard to claims 16, 31-33, 35, 38, 39, and 40, all the claims of application 08/253,843, and that these claims be FINALLY REFUSED.

FURTHER ORDERED that the parties are directed to 35 USC § 135(c) and Bd. R. 205 regarding the filing of settlement agreements; and

FURTHER ORDERED that a copy of this judgment shall be entered into the administrative record of Fiers application 08/253,843 and Sugano application 08/463,757.

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ADDENDUM 4

Leahy-Smith America Invents Act, Pub. L. No. 112-29, 125 Stat. 284
(284-341)

2014-1525
Biogen Idec MA, Inc.
v.
Japanese Foundation for Cancer Research and Bayer Pharma AG

125 STAT. 284

PUBLIC LAW 112-29—SEPT. 16, 2011

Public Law 112-29
112th Congress

An Act

Sept. 16, 2011

[H.R. 1249]

Leahy-Smith
America Invents
Act.

35 USC 1 note.

To amend title 35, United States Code, to provide for patent reform.

*Be it enacted by the Senate and House of Representatives of
the United States of America in Congress assembled,*

SECTION 1. SHORT TITLE; TABLE OF CONTENTS.

(a) **SHORT TITLE.**—This Act may be cited as the “Leahy-Smith America Invents Act”.

(b) **TABLE OF CONTENTS.**—The table of contents for this Act is as follows:

- Sec. 1. Short title; table of contents.
- Sec. 2. Definitions.
- Sec. 3. First inventor to file.
- Sec. 4. Inventor's oath or declaration.
- Sec. 5. Defense to infringement based on prior commercial use.
- Sec. 6. Post-grant review proceedings.
- Sec. 7. Patent Trial and Appeal Board.
- Sec. 8. Preissuance submissions by third parties.
- Sec. 9. Venue.
- Sec. 10. Fee setting authority.
- Sec. 11. Fees for patent services.
- Sec. 12. Supplemental examination.
- Sec. 13. Funding agreements.
- Sec. 14. Tax strategies deemed within the prior art.
- Sec. 15. Best mode requirement.
- Sec. 16. Marking.
- Sec. 17. Advice of counsel.
- Sec. 18. Transitional program for covered business method patents.
- Sec. 19. Jurisdiction and procedural matters.
- Sec. 20. Technical amendments.
- Sec. 21. Travel expenses and payment of administrative judges.
- Sec. 22. Patent and Trademark Office funding.
- Sec. 23. Satellite offices.
- Sec. 24. Designation of Detroit satellite office.
- Sec. 25. Priority examination for important technologies.
- Sec. 26. Study on implementation.
- Sec. 27. Study on genetic testing.
- Sec. 28. Patent Ombudsman Program for small business concerns.
- Sec. 29. Establishment of methods for studying the diversity of applicants.
- Sec. 30. Sense of Congress.
- Sec. 31. USPTO study on international patent protections for small businesses.
- Sec. 32. Pro bono program.
- Sec. 33. Limitation on issuance of patents.
- Sec. 34. Study of patent litigation.
- Sec. 35. Effective date.
- Sec. 36. Budgetary effects.
- Sec. 37. Calculation of 60-day period for application of patent term extension.

35 USC 1 note.

SEC. 2. DEFINITIONS.

In this Act:

(1) **DIRECTOR.**—The term “Director” means the Under Secretary of Commerce for Intellectual Property and Director of the United States Patent and Trademark Office.

(2) OFFICE.—The term “Office” means the United States Patent and Trademark Office.

(3) PATENT PUBLIC ADVISORY COMMITTEE.—The term “Patent Public Advisory Committee” means the Patent Public Advisory Committee established under section 5(a) of title 35, United States Code.

(4) TRADEMARK ACT OF 1946.—The term “Trademark Act of 1946” means the Act entitled “An Act to provide for the registration and protection of trademarks used in commerce, to carry out the provisions of certain international conventions, and for other purposes”, approved July 5, 1946 (15 U.S.C. 1051 et seq.) (commonly referred to as the “Trademark Act of 1946” or the “Lanham Act”).

(5) TRADEMARK PUBLIC ADVISORY COMMITTEE.—The term “Trademark Public Advisory Committee” means the Trademark Public Advisory Committee established under section 5(a) of title 35, United States Code.

SEC. 3. FIRST INVENTOR TO FILE.

(a) DEFINITIONS.—Section 100 of title 35, United States Code, is amended—

(1) in subsection (e), by striking “or inter partes reexamination under section 311”; and

(2) by adding at the end the following:

“(f) The term ‘inventor’ means the individual or, if a joint invention, the individuals collectively who invented or discovered the subject matter of the invention.

“(g) The terms ‘joint inventor’ and ‘coinventor’ mean any 1 of the individuals who invented or discovered the subject matter of a joint invention.

“(h) The term ‘joint research agreement’ means a written contract, grant, or cooperative agreement entered into by 2 or more persons or entities for the performance of experimental, developmental, or research work in the field of the claimed invention.

“(i)(1) The term ‘effective filing date’ for a claimed invention in a patent or application for patent means—

“(A) if subparagraph (B) does not apply, the actual filing date of the patent or the application for the patent containing a claim to the invention; or

“(B) the filing date of the earliest application for which the patent or application is entitled, as to such invention, to a right of priority under section 119, 365(a), or 365(b) or to the benefit of an earlier filing date under section 120, 121, or 365(c).

“(2) The effective filing date for a claimed invention in an application for reissue or reissued patent shall be determined by deeming the claim to the invention to have been contained in the patent for which reissue was sought.

“(j) The term ‘claimed invention’ means the subject matter defined by a claim in a patent or an application for a patent.”.

(b) CONDITIONS FOR PATENTABILITY.—

(1) IN GENERAL.—Section 102 of title 35, United States Code, is amended to read as follows:

“§ 102. Conditions for patentability; novelty

“(a) NOVELTY; PRIOR ART.—A person shall be entitled to a patent unless—

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“(1) the claimed invention was patented, described in a printed publication, or in public use, on sale, or otherwise available to the public before the effective filing date of the claimed invention; or

“(2) the claimed invention was described in a patent issued under section 151, or in an application for patent published or deemed published under section 122(b), in which the patent or application, as the case may be, names another inventor and was effectively filed before the effective filing date of the claimed invention.

“(b) EXCEPTIONS.—

“(1) DISCLOSURES MADE 1 YEAR OR LESS BEFORE THE EFFECTIVE FILING DATE OF THE CLAIMED INVENTION.—A disclosure made 1 year or less before the effective filing date of a claimed invention shall not be prior art to the claimed invention under subsection (a)(1) if—

“(A) the disclosure was made by the inventor or joint inventor or by another who obtained the subject matter disclosed directly or indirectly from the inventor or a joint inventor; or

“(B) the subject matter disclosed had, before such disclosure, been publicly disclosed by the inventor or a joint inventor or another who obtained the subject matter disclosed directly or indirectly from the inventor or a joint inventor.

“(2) DISCLOSURES APPEARING IN APPLICATIONS AND PATENTS.—A disclosure shall not be prior art to a claimed invention under subsection (a)(2) if—

“(A) the subject matter disclosed was obtained directly or indirectly from the inventor or a joint inventor;

“(B) the subject matter disclosed had, before such subject matter was effectively filed under subsection (a)(2), been publicly disclosed by the inventor or a joint inventor or another who obtained the subject matter disclosed directly or indirectly from the inventor or a joint inventor; or

“(C) the subject matter disclosed and the claimed invention, not later than the effective filing date of the claimed invention, were owned by the same person or subject to an obligation of assignment to the same person.

“(c) COMMON OWNERSHIP UNDER JOINT RESEARCH AGREEMENTS.—Subject matter disclosed and a claimed invention shall be deemed to have been owned by the same person or subject to an obligation of assignment to the same person in applying the provisions of subsection (b)(2)(C) if—

“(1) the subject matter disclosed was developed and the claimed invention was made by, or on behalf of, 1 or more parties to a joint research agreement that was in effect on or before the effective filing date of the claimed invention;

“(2) the claimed invention was made as a result of activities undertaken within the scope of the joint research agreement; and

“(3) the application for patent for the claimed invention discloses or is amended to disclose the names of the parties to the joint research agreement.

“(d) PATENTS AND PUBLISHED APPLICATIONS EFFECTIVE AS PRIOR ART.—For purposes of determining whether a patent or

application for patent is prior art to a claimed invention under subsection (a)(2), such patent or application shall be considered to have been effectively filed, with respect to any subject matter described in the patent or application—

“(1) if paragraph (2) does not apply, as of the actual filing date of the patent or the application for patent; or

“(2) if the patent or application for patent is entitled to claim a right of priority under section 119, 365(a), or 365(b), or to claim the benefit of an earlier filing date under section 120, 121, or 365(c), based upon 1 or more prior filed applications for patent, as of the filing date of the earliest such application that describes the subject matter.”.

(2) CONTINUITY OF INTENT UNDER THE CREATE ACT.—The enactment of section 102(c) of title 35, United States Code, under paragraph (1) of this subsection is done with the same intent to promote joint research activities that was expressed, including in the legislative history, through the enactment of the Cooperative Research and Technology Enhancement Act of 2004 (Public Law 108-453; the “CREATE Act”), the amendments of which are stricken by subsection (c) of this section. The United States Patent and Trademark Office shall administer section 102(c) of title 35, United States Code, in a manner consistent with the legislative history of the CREATE Act that was relevant to its administration by the United States Patent and Trademark Office.

35 USC 102 note.

(3) CONFORMING AMENDMENT.—The item relating to section 102 in the table of sections for chapter 10 of title 35, United States Code, is amended to read as follows:

“102. Conditions for patentability; novelty.”.

(c) CONDITIONS FOR PATENTABILITY; NONOBVIOUS SUBJECT MATTER.—Section 103 of title 35, United States Code, is amended to read as follows:

“§ 103. Conditions for patentability; non-obvious subject matter

“A patent for a claimed invention may not be obtained, notwithstanding that the claimed invention is not identically disclosed as set forth in section 102, if the differences between the claimed invention and the prior art are such that the claimed invention as a whole would have been obvious before the effective filing date of the claimed invention to a person having ordinary skill in the art to which the claimed invention pertains. Patentability shall not be negated by the manner in which the invention was made.”.

(d) REPEAL OF REQUIREMENTS FOR INVENTIONS MADE ABROAD.—Section 104 of title 35, United States Code, and the item relating to that section in the table of sections for chapter 10 of title 35, United States Code, are repealed.

(e) REPEAL OF STATUTORY INVENTION REGISTRATION.—

(1) IN GENERAL.—Section 157 of title 35, United States Code, and the item relating to that section in the table of sections for chapter 14 of title 35, United States Code, are repealed.

(2) REMOVAL OF CROSS REFERENCES.—Section 111(b)(8) of title 35, United States Code, is amended by striking “sections 115, 131, 135, and 157” and inserting “sections 131 and 135”.

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Applicability.
35 USC 111 note.

(3) **EFFECTIVE DATE.**—The amendments made by this subsection shall take effect upon the expiration of the 18-month period beginning on the date of the enactment of this Act, and shall apply to any request for a statutory invention registration filed on or after that effective date.

(f) **EARLIER FILING DATE FOR INVENTOR AND JOINT INVENTOR.**—Section 120 of title 35, United States Code, is amended by striking “which is filed by an inventor or inventors named” and inserting “which names an inventor or joint inventor”.

(g) **CONFORMING AMENDMENTS.**—

(1) **RIGHT OF PRIORITY.**—Section 172 of title 35, United States Code, is amended by striking “and the time specified in section 102(d)”.

(2) **LIMITATION ON REMEDIES.**—Section 287(c)(4) of title 35, United States Code, is amended by striking “the earliest effective filing date of which is prior to” and inserting “which has an effective filing date before”.

(3) **INTERNATIONAL APPLICATION DESIGNATING THE UNITED STATES: EFFECT.**—Section 363 of title 35, United States Code, is amended by striking “except as otherwise provided in section 102(e) of this title”.

(4) **PUBLICATION OF INTERNATIONAL APPLICATION: EFFECT.**—Section 374 of title 35, United States Code, is amended by striking “sections 102(e) and 154(d)” and inserting “section 154(d)”.

(5) **PATENT ISSUED ON INTERNATIONAL APPLICATION: EFFECT.**—The second sentence of section 375(a) of title 35, United States Code, is amended by striking “Subject to section 102(e) of this title, such” and inserting “Such”.

(6) **LIMIT ON RIGHT OF PRIORITY.**—Section 119(a) of title 35, United States Code, is amended by striking “; but no patent shall be granted” and all that follows through “one year prior to such filing”.

(7) **INVENTIONS MADE WITH FEDERAL ASSISTANCE.**—Section 202(c) of title 35, United States Code, is amended—

(A) in paragraph (2)—

(i) by striking “publication, on sale, or public use,” and all that follows through “obtained in the United States” and inserting “the 1-year period referred to in section 102(b) would end before the end of that 2-year period”; and

(ii) by striking “prior to the end of the statutory” and inserting “before the end of that 1-year”; and

(B) in paragraph (3), by striking “any statutory bar date that may occur under this title due to publication, on sale, or public use” and inserting “the expiration of the 1-year period referred to in section 102(b)”.

(h) **DERIVED PATENTS.**—

(1) **IN GENERAL.**—Section 291 of title 35, United States Code, is amended to read as follows:

“§ 291. Derived Patents

“(a) **IN GENERAL.**—The owner of a patent may have relief by civil action against the owner of another patent that claims the same invention and has an earlier effective filing date, if the invention claimed in such other patent was derived from the inventor

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of the invention claimed in the patent owned by the person seeking relief under this section.

“(b) FILING LIMITATION.—An action under this section may be filed only before the end of the 1-year period beginning on the date of the issuance of the first patent containing a claim to the allegedly derived invention and naming an individual alleged to have derived such invention as the inventor or joint inventor.” Time period.

(2) CONFORMING AMENDMENT.—The item relating to section 291 in the table of sections for chapter 29 of title 35, United States Code, is amended to read as follows:

“291. Derived patents.”.

(i) DERIVATION PROCEEDINGS.—Section 135 of title 35, United States Code, is amended to read as follows:

“§ 135. Derivation proceedings

“(a) INSTITUTION OF PROCEEDING.—An applicant for patent may file a petition to institute a derivation proceeding in the Office. The petition shall set forth with particularity the basis for finding that an inventor named in an earlier application derived the claimed invention from an inventor named in the petitioner’s application and, without authorization, the earlier application claiming such invention was filed. Any such petition may be filed only within the 1-year period beginning on the date of the first publication of a claim to an invention that is the same or substantially the same as the earlier application’s claim to the invention, shall be made under oath, and shall be supported by substantial evidence. Whenever the Director determines that a petition filed under this subsection demonstrates that the standards for instituting a derivation proceeding are met, the Director may institute a derivation proceeding. The determination by the Director whether to institute a derivation proceeding shall be final and nonappealable. Time period.

“(b) DETERMINATION BY PATENT TRIAL AND APPEAL BOARD.—In a derivation proceeding instituted under subsection (a), the Patent Trial and Appeal Board shall determine whether an inventor named in the earlier application derived the claimed invention from an inventor named in the petitioner’s application and, without authorization, the earlier application claiming such invention was filed. In appropriate circumstances, the Patent Trial and Appeal Board may correct the naming of the inventor in any application or patent at issue. The Director shall prescribe regulations setting forth standards for the conduct of derivation proceedings, including requiring parties to provide sufficient evidence to prove and rebut a claim of derivation. Regulations.

“(c) DEFERRAL OF DECISION.—The Patent Trial and Appeal Board may defer action on a petition for a derivation proceeding until the expiration of the 3-month period beginning on the date on which the Director issues a patent that includes the claimed invention that is the subject of the petition. The Patent Trial and Appeal Board also may defer action on a petition for a derivation proceeding, or stay the proceeding after it has been instituted, until the termination of a proceeding under chapter 30, 31, or 32 involving the patent of the earlier applicant. Time period.

“(d) EFFECT OF FINAL DECISION.—The final decision of the Patent Trial and Appeal Board, if adverse to claims in an application for patent, shall constitute the final refusal by the Office on those claims. The final decision of the Patent Trial and Appeal

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Board, if adverse to claims in a patent, shall, if no appeal or other review of the decision has been or can be taken or had, constitute cancellation of those claims, and notice of such cancellation shall be endorsed on copies of the patent distributed after such cancellation.

Confidentiality.

“(e) SETTLEMENT.—Parties to a proceeding instituted under subsection (a) may terminate the proceeding by filing a written statement reflecting the agreement of the parties as to the correct inventors of the claimed invention in dispute. Unless the Patent Trial and Appeal Board finds the agreement to be inconsistent with the evidence of record, if any, it shall take action consistent with the agreement. Any written settlement or understanding of the parties shall be filed with the Director. At the request of a party to the proceeding, the agreement or understanding shall be treated as business confidential information, shall be kept separate from the file of the involved patents or applications, and shall be made available only to Government agencies on written request, or to any person on a showing of good cause.

Regulations.

“(f) ARBITRATION.—Parties to a proceeding instituted under subsection (a) may, within such time as may be specified by the Director by regulation, determine such contest or any aspect thereof by arbitration. Such arbitration shall be governed by the provisions of title 9, to the extent such title is not inconsistent with this section. The parties shall give notice of any arbitration award to the Director, and such award shall, as between the parties to the arbitration, be dispositive of the issues to which it relates. The arbitration award shall be unenforceable until such notice is given. Nothing in this subsection shall preclude the Director from determining the patentability of the claimed inventions involved in the proceeding.”.

Notice.

(j) ELIMINATION OF REFERENCES TO INTERFERENCES.—(1) Sections 134, 145, 146, 154, and 305 of title 35, United States Code, are each amended by striking “Board of Patent Appeals and Interferences” each place it appears and inserting “Patent Trial and Appeal Board”.

(2)(A) Section 146 of title 35, United States Code, is amended—

(i) by striking “an interference” and inserting “a derivation proceeding”; and

(ii) by striking “the interference” and inserting “the derivation proceeding”.

(B) The subparagraph heading for section 154(b)(1)(C) of title 35, United States Code, is amended to read as follows:

“(C) GUARANTEE OF ADJUSTMENTS FOR DELAYS DUE TO DERIVATION PROCEEDINGS, SECRECY ORDERS, AND APPEALS.—”.

(3) The section heading for section 134 of title 35, United States Code, is amended to read as follows:

“§ 134. Appeal to the Patent Trial and Appeal Board”.

(4) The section heading for section 146 of title 35, United States Code, is amended to read as follows:

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“§ 146. Civil action in case of derivation proceeding”.

(5) The items relating to sections 134 and 135 in the table of sections for chapter 12 of title 35, United States Code, are amended to read as follows:

“134. Appeal to the Patent Trial and Appeal Board.

“135. Derivation proceedings.”.

(6) The item relating to section 146 in the table of sections for chapter 13 of title 35, United States Code, is amended to read as follows:

“146. Civil action in case of derivation proceeding.”.

(k) STATUTE OF LIMITATIONS.—

(1) IN GENERAL.—Section 32 of title 35, United States Code, is amended by inserting between the third and fourth sentences the following: “A proceeding under this section shall be commenced not later than the earlier of either the date that is 10 years after the date on which the misconduct forming the basis for the proceeding occurred, or 1 year after the date on which the misconduct forming the basis for the proceeding is made known to an officer or employee of the Office as prescribed in the regulations established under section 2(b)(2)(D).”.

(2) REPORT TO CONGRESS.—The Director shall provide on a biennial basis to the Judiciary Committees of the Senate and House of Representatives a report providing a short description of incidents made known to an officer or employee of the Office as prescribed in the regulations established under section 2(b)(2)(D) of title 35, United States Code, that reflect substantial evidence of misconduct before the Office but for which the Office was barred from commencing a proceeding under section 32 of title 35, United States Code, by the time limitation established by the fourth sentence of that section.

35 USC 32 note.

(3) EFFECTIVE DATE.—The amendment made by paragraph (1) shall apply in any case in which the time period for instituting a proceeding under section 32 of title 35, United States Code, had not lapsed before the date of the enactment of this Act.

35 USC 32 note.

(l) SMALL BUSINESS STUDY.—

(1) DEFINITIONS.—In this subsection—

(A) the term “Chief Counsel” means the Chief Counsel for Advocacy of the Small Business Administration;

(B) the term “General Counsel” means the General Counsel of the United States Patent and Trademark Office; and

(C) the term “small business concern” has the meaning given that term under section 3 of the Small Business Act (15 U.S.C. 632).

(2) STUDY.—

(A) IN GENERAL.—The Chief Counsel, in consultation with the General Counsel, shall conduct a study of the effects of eliminating the use of dates of invention in determining whether an applicant is entitled to a patent under title 35, United States Code.

(B) AREAS OF STUDY.—The study conducted under subparagraph (A) shall include examination of the effects

of eliminating the use of invention dates, including examining—

(i) how the change would affect the ability of small business concerns to obtain patents and their costs of obtaining patents;

(ii) whether the change would create, mitigate, or exacerbate any disadvantages for applicants for patents that are small business concerns relative to applicants for patents that are not small business concerns, and whether the change would create any advantages for applicants for patents that are small business concerns relative to applicants for patents that are not small business concerns;

(iii) the cost savings and other potential benefits to small business concerns of the change; and

(iv) the feasibility and costs and benefits to small business concerns of alternative means of determining whether an applicant is entitled to a patent under title 35, United States Code.

(3) REPORT.—Not later than the date that is 1 year after the date of the enactment of this Act, the Chief Counsel shall submit to the Committee on Small Business and Entrepreneurship and the Committee on the Judiciary of the Senate and the Committee on Small Business and the Committee on the Judiciary of the House of Representatives a report on the results of the study under paragraph (2).

(m) REPORT ON PRIOR USER RIGHTS.—

(1) IN GENERAL.—Not later than the end of the 4-month period beginning on the date of the enactment of this Act, the Director shall report, to the Committee on the Judiciary of the Senate and the Committee on the Judiciary of the House of Representatives, the findings and recommendations of the Director on the operation of prior user rights in selected countries in the industrialized world. The report shall include the following:

(A) A comparison between patent laws of the United States and the laws of other industrialized countries, including members of the European Union and Japan, Canada, and Australia.

(B) An analysis of the effect of prior user rights on innovation rates in the selected countries.

(C) An analysis of the correlation, if any, between prior user rights and start-up enterprises and the ability to attract venture capital to start new companies.

(D) An analysis of the effect of prior user rights, if any, on small businesses, universities, and individual inventors.

(E) An analysis of legal and constitutional issues, if any, that arise from placing trade secret law in patent law.

(F) An analysis of whether the change to a first-to-file patent system creates a particular need for prior user rights.

(2) CONSULTATION WITH OTHER AGENCIES.—In preparing the report required under paragraph (1), the Director shall consult with the United States Trade Representative, the Secretary of State, and the Attorney General.

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(n) EFFECTIVE DATE.—

Applicability.
35 USC 100 note.

(1) IN GENERAL.—Except as otherwise provided in this section, the amendments made by this section shall take effect upon the expiration of the 18-month period beginning on the date of the enactment of this Act, and shall apply to any application for patent, and to any patent issuing thereon, that contains or contained at any time—

(A) a claim to a claimed invention that has an effective filing date as defined in section 100(i) of title 35, United States Code, that is on or after the effective date described in this paragraph; or

(B) a specific reference under section 120, 121, or 365(c) of title 35, United States Code, to any patent or application that contains or contained at any time such a claim.

(2) INTERFERING PATENTS.—The provisions of sections 102(g), 135, and 291 of title 35, United States Code, as in effect on the day before the effective date set forth in paragraph (1) of this subsection, shall apply to each claim of an application for patent, and any patent issued thereon, for which the amendments made by this section also apply, if such application or patent contains or contained at any time—

(A) a claim to an invention having an effective filing date as defined in section 100(i) of title 35, United States Code, that occurs before the effective date set forth in paragraph (1) of this subsection; or

(B) a specific reference under section 120, 121, or 365(c) of title 35, United States Code, to any patent or application that contains or contained at any time such a claim.

(o) SENSE OF CONGRESS.—It is the sense of the Congress that converting the United States patent system from “first to invent” to a system of “first inventor to file” will promote the progress of science and the useful arts by securing for limited times to inventors the exclusive rights to their discoveries and provide inventors with greater certainty regarding the scope of protection provided by the grant of exclusive rights to their discoveries.

(p) SENSE OF CONGRESS.—It is the sense of the Congress that converting the United States patent system from “first to invent” to a system of “first inventor to file” will improve the United States patent system and promote harmonization of the United States patent system with the patent systems commonly used in nearly all other countries throughout the world with whom the United States conducts trade and thereby promote greater international uniformity and certainty in the procedures used for securing the exclusive rights of inventors to their discoveries.

SEC. 4. INVENTOR'S OATH OR DECLARATION.

(a) INVENTOR'S OATH OR DECLARATION.—

(1) IN GENERAL.—Section 115 of title 35, United States Code, is amended to read as follows:

“§ 115. Inventor's oath or declaration

“(a) NAMING THE INVENTOR; INVENTOR'S OATH OR DECLARATION.—An application for patent that is filed under section 111(a) or commences the national stage under section 371 shall include, or be amended to include, the name of the inventor for any invention claimed in the application. Except as otherwise provided in this section, each individual who is the inventor or a joint inventor

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of a claimed invention in an application for patent shall execute an oath or declaration in connection with the application.

“(b) REQUIRED STATEMENTS.—An oath or declaration under subsection (a) shall contain statements that—

“(1) the application was made or was authorized to be made by the affiant or declarant; and

“(2) such individual believes himself or herself to be the original inventor or an original joint inventor of a claimed invention in the application.

“(c) ADDITIONAL REQUIREMENTS.—The Director may specify additional information relating to the inventor and the invention that is required to be included in an oath or declaration under subsection (a).

“(d) SUBSTITUTE STATEMENT.—

Regulations.

“(1) IN GENERAL.—In lieu of executing an oath or declaration under subsection (a), the applicant for patent may provide a substitute statement under the circumstances described in paragraph (2) and such additional circumstances that the Director may specify by regulation.

“(2) PERMITTED CIRCUMSTANCES.—A substitute statement under paragraph (1) is permitted with respect to any individual who—

“(A) is unable to file the oath or declaration under subsection (a) because the individual—

“(i) is deceased;

“(ii) is under legal incapacity; or

“(iii) cannot be found or reached after diligent effort; or

“(B) is under an obligation to assign the invention but has refused to make the oath or declaration required under subsection (a).

“(3) CONTENTS.—A substitute statement under this subsection shall—

“(A) identify the individual with respect to whom the statement applies;

“(B) set forth the circumstances representing the permitted basis for the filing of the substitute statement in lieu of the oath or declaration under subsection (a); and

“(C) contain any additional information, including any showing, required by the Director.

“(e) MAKING REQUIRED STATEMENTS IN ASSIGNMENT OF RECORD.—An individual who is under an obligation of assignment of an application for patent may include the required statements under subsections (b) and (c) in the assignment executed by the individual, in lieu of filing such statements separately.

“(f) TIME FOR FILING.—A notice of allowance under section 151 may be provided to an applicant for patent only if the applicant for patent has filed each required oath or declaration under subsection (a) or has filed a substitute statement under subsection (d) or recorded an assignment meeting the requirements of subsection (e).

“(g) EARLIER-FILED APPLICATION CONTAINING REQUIRED STATEMENTS OR SUBSTITUTE STATEMENT.—

“(1) EXCEPTION.—The requirements under this section shall not apply to an individual with respect to an application for patent in which the individual is named as the inventor or

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a joint inventor and who claims the benefit under section 120, 121, or 365(c) of the filing of an earlier-filed application, if—

“(A) an oath or declaration meeting the requirements of subsection (a) was executed by the individual and was filed in connection with the earlier-filed application;

“(B) a substitute statement meeting the requirements of subsection (d) was filed in connection with the earlier filed application with respect to the individual; or

“(C) an assignment meeting the requirements of subsection (e) was executed with respect to the earlier-filed application by the individual and was recorded in connection with the earlier-filed application.

“(2) COPIES OF OATHS, DECLARATIONS, STATEMENTS, OR ASSIGNMENTS.—Notwithstanding paragraph (1), the Director may require that a copy of the executed oath or declaration, the substitute statement, or the assignment filed in connection with the earlier-filed application be included in the later-filed application.

“(h) SUPPLEMENTAL AND CORRECTED STATEMENTS; FILING ADDITIONAL STATEMENTS.—

“(1) IN GENERAL.—Any person making a statement required under this section may withdraw, replace, or otherwise correct the statement at any time. If a change is made in the naming of the inventor requiring the filing of 1 or more additional statements under this section, the Director shall establish regulations under which such additional statements may be filed.

Regulations.

“(2) SUPPLEMENTAL STATEMENTS NOT REQUIRED.—If an individual has executed an oath or declaration meeting the requirements of subsection (a) or an assignment meeting the requirements of subsection (e) with respect to an application for patent, the Director may not thereafter require that individual to make any additional oath, declaration, or other statement equivalent to those required by this section in connection with the application for patent or any patent issuing thereon.

“(3) SAVINGS CLAUSE.—A patent shall not be invalid or unenforceable based upon the failure to comply with a requirement under this section if the failure is remedied as provided under paragraph (1).

“(i) ACKNOWLEDGMENT OF PENALTIES.—Any declaration or statement filed pursuant to this section shall contain an acknowledgment that any willful false statement made in such declaration or statement is punishable under section 1001 of title 18 by fine or imprisonment of not more than 5 years, or both.”.

(2) RELATIONSHIP TO DIVISIONAL APPLICATIONS.—Section 121 of title 35, United States Code, is amended by striking “If a divisional application” and all that follows through “inventor.”.

(3) REQUIREMENTS FOR NONPROVISIONAL APPLICATIONS.—Section 111(a) of title 35, United States Code, is amended—

(A) in paragraph (2)(C), by striking “by the applicant” and inserting “or declaration”;

(B) in the heading for paragraph (3), by inserting “OR DECLARATION” after “AND OATH”; and

(C) by inserting “or declaration” after “and oath” each place it appears.

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(4) CONFORMING AMENDMENT.—The item relating to section 115 in the table of sections for chapter 11 of title 35, United States Code, is amended to read as follows:

“115. Inventor’s oath or declaration.”.

(b) FILING BY OTHER THAN INVENTOR.—

(1) IN GENERAL.—Section 118 of title 35, United States Code, is amended to read as follows:

“§ 118. Filing by other than inventor

“A person to whom the inventor has assigned or is under an obligation to assign the invention may make an application for patent. A person who otherwise shows sufficient proprietary interest in the matter may make an application for patent on behalf of and as agent for the inventor on proof of the pertinent facts and a showing that such action is appropriate to preserve the rights of the parties. If the Director grants a patent on an application filed under this section by a person other than the inventor, the patent shall be granted to the real party in interest and upon such notice to the inventor as the Director considers to be sufficient.”.

(2) CONFORMING AMENDMENT.—Section 251 of title 35, United States Code, is amended in the third undesignated paragraph by inserting “or the application for the original patent was filed by the assignee of the entire interest” after “claims of the original patent”.

(c) SPECIFICATION.—Section 112 of title 35, United States Code, is amended—

(1) in the first undesignated paragraph—

(A) by striking “The specification” and inserting “(a) IN GENERAL.—The specification”; and

(B) by striking “of carrying out his invention” and inserting “or joint inventor of carrying out the invention”;

(2) in the second undesignated paragraph—

(A) by striking “The specification” and inserting “(b) CONCLUSION.—The specification”; and

(B) by striking “applicant regards as his invention” and inserting “inventor or a joint inventor regards as the invention”;

(3) in the third undesignated paragraph, by striking “A claim” and inserting “(c) FORM.—A claim”;

(4) in the fourth undesignated paragraph, by striking “Subject to the following paragraph,” and inserting “(d) REFERENCE IN DEPENDENT FORMS.—Subject to subsection (e),”;

(5) in the fifth undesignated paragraph, by striking “A claim” and inserting “(e) REFERENCE IN MULTIPLE DEPENDENT FORM.—A claim”; and

(6) in the last undesignated paragraph, by striking “An element” and inserting “(f) ELEMENT IN CLAIM FOR A COMBINATION.—An element”.

(d) CONFORMING AMENDMENTS.—

(1) Sections 111(b)(1)(A) of title 35, United States Code, is amended by striking “the first paragraph of section 112 of this title” and inserting “section 112(a)”.

(2) Section 111(b)(2) of title 35, United States Code, is amended by striking “the second through fifth paragraphs of

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section 112,” and inserting “subsections (b) through (e) of section 112,”.

(e) EFFECTIVE DATE.—The amendments made by this section shall take effect upon the expiration of the 1-year period beginning on the date of the enactment of this Act and shall apply to any patent application that is filed on or after that effective date.

Applicability.
35 USC 111 note.

SEC. 5. DEFENSE TO INFRINGEMENT BASED ON PRIOR COMMERCIAL USE.

(a) IN GENERAL.—Section 273 of title 35, United States Code, is amended to read as follows:

“§ 273. Defense to infringement based on prior commercial use

“(a) IN GENERAL.—A person shall be entitled to a defense under section 282(b) with respect to subject matter consisting of a process, or consisting of a machine, manufacture, or composition of matter used in a manufacturing or other commercial process, that would otherwise infringe a claimed invention being asserted against the person if—

“(1) such person, acting in good faith, commercially used the subject matter in the United States, either in connection with an internal commercial use or an actual arm’s length sale or other arm’s length commercial transfer of a useful end result of such commercial use; and

“(2) such commercial use occurred at least 1 year before the earlier of either—

“(A) the effective filing date of the claimed invention;

or

“(B) the date on which the claimed invention was disclosed to the public in a manner that qualified for the exception from prior art under section 102(b).

“(b) BURDEN OF PROOF.—A person asserting a defense under this section shall have the burden of establishing the defense by clear and convincing evidence.

“(c) ADDITIONAL COMMERCIAL USES.—

“(1) PREMARKETING REGULATORY REVIEW.—Subject matter for which commercial marketing or use is subject to a premarketing regulatory review period during which the safety or efficacy of the subject matter is established, including any period specified in section 156(g), shall be deemed to be commercially used for purposes of subsection (a)(1) during such regulatory review period.

“(2) NONPROFIT LABORATORY USE.—A use of subject matter by a nonprofit research laboratory or other nonprofit entity, such as a university or hospital, for which the public is the intended beneficiary, shall be deemed to be a commercial use for purposes of subsection (a)(1), except that a defense under this section may be asserted pursuant to this paragraph only for continued and noncommercial use by and in the laboratory or other nonprofit entity.

“(d) EXHAUSTION OF RIGHTS.—Notwithstanding subsection (e)(1), the sale or other disposition of a useful end result by a person entitled to assert a defense under this section in connection with a patent with respect to that useful end result shall exhaust the patent owner’s rights under the patent to the extent that

such rights would have been exhausted had such sale or other disposition been made by the patent owner.

“(e) LIMITATIONS AND EXCEPTIONS.—

“(1) PERSONAL DEFENSE.—

“(A) IN GENERAL.—A defense under this section may be asserted only by the person who performed or directed the performance of the commercial use described in subsection (a), or by an entity that controls, is controlled by, or is under common control with such person.

“(B) TRANSFER OF RIGHT.—Except for any transfer to the patent owner, the right to assert a defense under this section shall not be licensed or assigned or transferred to another person except as an ancillary and subordinate part of a good-faith assignment or transfer for other reasons of the entire enterprise or line of business to which the defense relates.

“(C) RESTRICTION ON SITES.—A defense under this section, when acquired by a person as part of an assignment or transfer described in subparagraph (B), may only be asserted for uses at sites where the subject matter that would otherwise infringe a claimed invention is in use before the later of the effective filing date of the claimed invention or the date of the assignment or transfer of such enterprise or line of business.

“(2) DERIVATION.—A person may not assert a defense under this section if the subject matter on which the defense is based was derived from the patentee or persons in privity with the patentee.

“(3) NOT A GENERAL LICENSE.—The defense asserted by a person under this section is not a general license under all claims of the patent at issue, but extends only to the specific subject matter for which it has been established that a commercial use that qualifies under this section occurred, except that the defense shall also extend to variations in the quantity or volume of use of the claimed subject matter, and to improvements in the claimed subject matter that do not infringe additional specifically claimed subject matter of the patent.

“(4) ABANDONMENT OF USE.—A person who has abandoned commercial use (that qualifies under this section) of subject matter may not rely on activities performed before the date of such abandonment in establishing a defense under this section with respect to actions taken on or after the date of such abandonment.

“(5) UNIVERSITY EXCEPTION.—

“(A) IN GENERAL.—A person commercially using subject matter to which subsection (a) applies may not assert a defense under this section if the claimed invention with respect to which the defense is asserted was, at the time the invention was made, owned or subject to an obligation of assignment to either an institution of higher education (as defined in section 101(a) of the Higher Education Act of 1965 (20 U.S.C. 1001(a)), or a technology transfer organization whose primary purpose is to facilitate the commercialization of technologies developed by one or more such institutions of higher education.

“(B) EXCEPTION.—Subparagraph (A) shall not apply if any of the activities required to reduce to practice the subject matter of the claimed invention could not have been undertaken using funds provided by the Federal Government.

“(f) UNREASONABLE ASSERTION OF DEFENSE.—If the defense under this section is pleaded by a person who is found to infringe the patent and who subsequently fails to demonstrate a reasonable basis for asserting the defense, the court shall find the case exceptional for the purpose of awarding attorney fees under section 285.

“(g) INVALIDITY.—A patent shall not be deemed to be invalid under section 102 or 103 solely because a defense is raised or established under this section.”.

(b) CONFORMING AMENDMENT.—The item relating to section 273 in the table of sections for chapter 28 of title 35, United States Code, is amended to read as follows:

“273. Defense to infringement based on prior commercial use.”.

(c) EFFECTIVE DATE.—The amendments made by this section shall apply to any patent issued on or after the date of the enactment of this Act.

Applicability.
35 USC 273 note.

SEC. 6. POST-GRANT REVIEW PROCEEDINGS.

(a) INTER PARTES REVIEW.—Chapter 31 of title 35, United States Code, is amended to read as follows:

“CHAPTER 31—INTER PARTES REVIEW

“Sec.

“311. Inter partes review.

“312. Petitions.

“313. Preliminary response to petition.

“314. Institution of inter partes review.

“315. Relation to other proceedings or actions.

“316. Conduct of inter partes review.

“317. Settlement.

“318. Decision of the Board.

“319. Appeal.

“§ 311. Inter partes review

“(a) IN GENERAL.—Subject to the provisions of this chapter, a person who is not the owner of a patent may file with the Office a petition to institute an inter partes review of the patent. The Director shall establish, by regulation, fees to be paid by the person requesting the review, in such amounts as the Director determines to be reasonable, considering the aggregate costs of the review.

Regulations.

“(b) SCOPE.—A petitioner in an inter partes review may request to cancel as unpatentable 1 or more claims of a patent only on a ground that could be raised under section 102 or 103 and only on the basis of prior art consisting of patents or printed publications.

“(c) FILING DEADLINE.—A petition for inter partes review shall be filed after the later of either—

“(1) the date that is 9 months after the grant of a patent or issuance of a reissue of a patent; or

“(2) if a post-grant review is instituted under chapter 32, the date of the termination of such post-grant review.

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“§ 312. Petitions

“(a) REQUIREMENTS OF PETITION.—A petition filed under section 311 may be considered only if—

“(1) the petition is accompanied by payment of the fee established by the Director under section 311;

“(2) the petition identifies all real parties in interest;

“(3) the petition identifies, in writing and with particularity, each claim challenged, the grounds on which the challenge to each claim is based, and the evidence that supports the grounds for the challenge to each claim, including—

“(A) copies of patents and printed publications that the petitioner relies upon in support of the petition; and

“(B) affidavits or declarations of supporting evidence and opinions, if the petitioner relies on expert opinions;

“(4) the petition provides such other information as the Director may require by regulation; and

“(5) the petitioner provides copies of any of the documents required under paragraphs (2), (3), and (4) to the patent owner or, if applicable, the designated representative of the patent owner.

“(b) PUBLIC AVAILABILITY.—As soon as practicable after the receipt of a petition under section 311, the Director shall make the petition available to the public.

“§ 313. Preliminary response to petition

“If an inter partes review petition is filed under section 311, the patent owner shall have the right to file a preliminary response to the petition, within a time period set by the Director, that sets forth reasons why no inter partes review should be instituted based upon the failure of the petition to meet any requirement of this chapter.

“§ 314. Institution of inter partes review

“(a) THRESHOLD.—The Director may not authorize an inter partes review to be instituted unless the Director determines that the information presented in the petition filed under section 311 and any response filed under section 313 shows that there is a reasonable likelihood that the petitioner would prevail with respect to at least 1 of the claims challenged in the petition.

“(b) TIMING.—The Director shall determine whether to institute an inter partes review under this chapter pursuant to a petition filed under section 311 within 3 months after—

“(1) receiving a preliminary response to the petition under section 313; or

“(2) if no such preliminary response is filed, the last date on which such response may be filed.

“(c) NOTICE.—The Director shall notify the petitioner and patent owner, in writing, of the Director’s determination under subsection (a), and shall make such notice available to the public as soon as is practicable. Such notice shall include the date on which the review shall commence.

“(d) NO APPEAL.—The determination by the Director whether to institute an inter partes review under this section shall be final and nonappealable.

“§ 315. Relation to other proceedings or actions

“(a) INFRINGER’S CIVIL ACTION.—

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“(1) INTER PARTES REVIEW BARRED BY CIVIL ACTION.—An inter partes review may not be instituted if, before the date on which the petition for such a review is filed, the petitioner or real party in interest filed a civil action challenging the validity of a claim of the patent.

“(2) STAY OF CIVIL ACTION.—If the petitioner or real party in interest files a civil action challenging the validity of a claim of the patent on or after the date on which the petitioner files a petition for inter partes review of the patent, that civil action shall be automatically stayed until either—

“(A) the patent owner moves the court to lift the stay;

“(B) the patent owner files a civil action or counterclaim alleging that the petitioner or real party in interest has infringed the patent; or

“(C) the petitioner or real party in interest moves the court to dismiss the civil action.

“(3) TREATMENT OF COUNTERCLAIM.—A counterclaim challenging the validity of a claim of a patent does not constitute a civil action challenging the validity of a claim of a patent for purposes of this subsection.

“(b) PATENT OWNER’S ACTION.—An inter partes review may not be instituted if the petition requesting the proceeding is filed more than 1 year after the date on which the petitioner, real party in interest, or privy of the petitioner is served with a complaint alleging infringement of the patent. The time limitation set forth in the preceding sentence shall not apply to a request for joinder under subsection (c).

Deadline.

“(c) JOINDER.—If the Director institutes an inter partes review, the Director, in his or her discretion, may join as a party to that inter partes review any person who properly files a petition under section 311 that the Director, after receiving a preliminary response under section 313 or the expiration of the time for filing such a response, determines warrants the institution of an inter partes review under section 314.

“(d) MULTIPLE PROCEEDINGS.—Notwithstanding sections 135(a), 251, and 252, and chapter 30, during the pendency of an inter partes review, if another proceeding or matter involving the patent is before the Office, the Director may determine the manner in which the inter partes review or other proceeding or matter may proceed, including providing for stay, transfer, consolidation, or termination of any such matter or proceeding.

“(e) ESTOPPEL.—

“(1) PROCEEDINGS BEFORE THE OFFICE.—The petitioner in an inter partes review of a claim in a patent under this chapter that results in a final written decision under section 318(a), or the real party in interest or privy of the petitioner, may not request or maintain a proceeding before the Office with respect to that claim on any ground that the petitioner raised or reasonably could have raised during that inter partes review.

“(2) CIVIL ACTIONS AND OTHER PROCEEDINGS.—The petitioner in an inter partes review of a claim in a patent under this chapter that results in a final written decision under section 318(a), or the real party in interest or privy of the petitioner, may not assert either in a civil action arising in whole or in part under section 1338 of title 28 or in a proceeding before the International Trade Commission under section 337 of the Tariff Act of 1930 that the claim is invalid on any

ground that the petitioner raised or reasonably could have raised during that inter partes review.

“§ 316. Conduct of inter partes review

“(a) REGULATIONS.—The Director shall prescribe regulations—

“(1) providing that the file of any proceeding under this chapter shall be made available to the public, except that any petition or document filed with the intent that it be sealed shall, if accompanied by a motion to seal, be treated as sealed pending the outcome of the ruling on the motion;

“(2) setting forth the standards for the showing of sufficient grounds to institute a review under section 314(a);

“(3) establishing procedures for the submission of supplemental information after the petition is filed;

“(4) establishing and governing inter partes review under this chapter and the relationship of such review to other proceedings under this title;

“(5) setting forth standards and procedures for discovery of relevant evidence, including that such discovery shall be limited to—

“(A) the deposition of witnesses submitting affidavits or declarations; and

“(B) what is otherwise necessary in the interest of justice;

“(6) prescribing sanctions for abuse of discovery, abuse of process, or any other improper use of the proceeding, such as to harass or to cause unnecessary delay or an unnecessary increase in the cost of the proceeding;

“(7) providing for protective orders governing the exchange and submission of confidential information;

“(8) providing for the filing by the patent owner of a response to the petition under section 313 after an inter partes review has been instituted, and requiring that the patent owner file with such response, through affidavits or declarations, any additional factual evidence and expert opinions on which the patent owner relies in support of the response;

“(9) setting forth standards and procedures for allowing the patent owner to move to amend the patent under subsection (d) to cancel a challenged claim or propose a reasonable number of substitute claims, and ensuring that any information submitted by the patent owner in support of any amendment entered under subsection (d) is made available to the public as part of the prosecution history of the patent;

“(10) providing either party with the right to an oral hearing as part of the proceeding;

“(11) requiring that the final determination in an inter partes review be issued not later than 1 year after the date on which the Director notices the institution of a review under this chapter, except that the Director may, for good cause shown, extend the 1-year period by not more than 6 months, and may adjust the time periods in this paragraph in the case of joinder under section 315(c);

“(12) setting a time period for requesting joinder under section 315(c); and

“(13) providing the petitioner with at least 1 opportunity to file written comments within a time period established by the Director.

“(b) CONSIDERATIONS.—In prescribing regulations under this section, the Director shall consider the effect of any such regulation on the economy, the integrity of the patent system, the efficient administration of the Office, and the ability of the Office to timely complete proceedings instituted under this chapter.

“(c) PATENT TRIAL AND APPEAL BOARD.—The Patent Trial and Appeal Board shall, in accordance with section 6, conduct each inter partes review instituted under this chapter.

“(d) AMENDMENT OF THE PATENT.—

“(1) IN GENERAL.—During an inter partes review instituted under this chapter, the patent owner may file 1 motion to amend the patent in 1 or more of the following ways:

“(A) Cancel any challenged patent claim.

“(B) For each challenged claim, propose a reasonable number of substitute claims.

“(2) ADDITIONAL MOTIONS.—Additional motions to amend may be permitted upon the joint request of the petitioner and the patent owner to materially advance the settlement of a proceeding under section 317, or as permitted by regulations prescribed by the Director.

“(3) SCOPE OF CLAIMS.—An amendment under this subsection may not enlarge the scope of the claims of the patent or introduce new matter.

“(e) EVIDENTIARY STANDARDS.—In an inter partes review instituted under this chapter, the petitioner shall have the burden of proving a proposition of unpatentability by a preponderance of the evidence.

“§ 317. Settlement

“(a) IN GENERAL.—An inter partes review instituted under this chapter shall be terminated with respect to any petitioner upon the joint request of the petitioner and the patent owner, unless the Office has decided the merits of the proceeding before the request for termination is filed. If the inter partes review is terminated with respect to a petitioner under this section, no estoppel under section 315(e) shall attach to the petitioner, or to the real party in interest or privy of the petitioner, on the basis of that petitioner’s institution of that inter partes review. If no petitioner remains in the inter partes review, the Office may terminate the review or proceed to a final written decision under section 318(a).

“(b) AGREEMENTS IN WRITING.—Any agreement or understanding between the patent owner and a petitioner, including any collateral agreements referred to in such agreement or understanding, made in connection with, or in contemplation of, the termination of an inter partes review under this section shall be in writing and a true copy of such agreement or understanding shall be filed in the Office before the termination of the inter partes review as between the parties. At the request of a party to the proceeding, the agreement or understanding shall be treated as business confidential information, shall be kept separate from the file of the involved patents, and shall be made available only to Federal Government agencies on written request, or to any person on a showing of good cause.

Confidentiality.

“§ 318. Decision of the Board

“(a) FINAL WRITTEN DECISION.—If an inter partes review is instituted and not dismissed under this chapter, the Patent Trial

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and Appeal Board shall issue a final written decision with respect to the patentability of any patent claim challenged by the petitioner and any new claim added under section 316(d).

“(b) CERTIFICATE.—If the Patent Trial and Appeal Board issues a final written decision under subsection (a) and the time for appeal has expired or any appeal has terminated, the Director shall issue and publish a certificate canceling any claim of the patent finally determined to be unpatentable, confirming any claim of the patent determined to be patentable, and incorporating in the patent by operation of the certificate any new or amended claim determined to be patentable.

“(c) INTERVENING RIGHTS.—Any proposed amended or new claim determined to be patentable and incorporated into a patent following an inter partes review under this chapter shall have the same effect as that specified in section 252 for reissued patents on the right of any person who made, purchased, or used within the United States, or imported into the United States, anything patented by such proposed amended or new claim, or who made substantial preparation therefor, before the issuance of a certificate under subsection (b).

Public
information.

“(d) DATA ON LENGTH OF REVIEW.—The Office shall make available to the public data describing the length of time between the institution of, and the issuance of a final written decision under subsection (a) for, each inter partes review.

“§ 319. Appeal

“A party dissatisfied with the final written decision of the Patent Trial and Appeal Board under section 318(a) may appeal the decision pursuant to sections 141 through 144. Any party to the inter partes review shall have the right to be a party to the appeal.”.

(b) CONFORMING AMENDMENT.—The table of chapters for part III of title 35, United States Code, is amended by striking the item relating to chapter 31 and inserting the following:

“31. Inter Partes Review 311”.

(c) REGULATIONS AND EFFECTIVE DATE.—

35 USC 311 note.

(1) REGULATIONS.—The Director shall, not later than the date that is 1 year after the date of the enactment of this Act, issue regulations to carry out chapter 31 of title 35, United States Code, as amended by subsection (a) of this section.

35 USC 311 note.

(2) APPLICABILITY.—

(A) IN GENERAL.—The amendments made by subsection (a) shall take effect upon the expiration of the 1-year period beginning on the date of the enactment of this Act and shall apply to any patent issued before, on, or after that effective date.

(B) GRADUATED IMPLEMENTATION.—The Director may impose a limit on the number of inter partes reviews that may be instituted under chapter 31 of title 35, United States Code, during each of the first 4 1-year periods in which the amendments made by subsection (a) are in effect, if such number in each year equals or exceeds the number of inter partes reexaminations that are ordered under chapter 31 of title 35, United States Code, in the last fiscal year ending before the effective date of the amendments made by subsection (a).

(3) TRANSITION.—

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(A) IN GENERAL.—Chapter 31 of title 35, United States Code, is amended—

(i) in section 312—

(I) in subsection (a)—

(aa) in the first sentence, by striking “a substantial new question of patentability affecting any claim of the patent concerned is raised by the request,” and inserting “the information presented in the request shows that there is a reasonable likelihood that the requester would prevail with respect to at least 1 of the claims challenged in the request,”; and

(bb) in the second sentence, by striking “The existence of a substantial new question of patentability” and inserting “A showing that there is a reasonable likelihood that the requester would prevail with respect to at least 1 of the claims challenged in the request”; and

(II) in subsection (c), in the second sentence, by striking “no substantial new question of patentability has been raised,” and inserting “the showing required by subsection (a) has not been made,”; and

(ii) in section 313, by striking “a substantial new question of patentability affecting a claim of the patent is raised” and inserting “it has been shown that there is a reasonable likelihood that the requester would prevail with respect to at least 1 of the claims challenged in the request”.

(B) APPLICATION.—The amendments made by this paragraph— 35 USC 312 note.

(i) shall take effect on the date of the enactment of this Act; and

(ii) shall apply to requests for inter partes reexamination that are filed on or after such date of enactment, but before the effective date set forth in paragraph (2)(A) of this subsection.

(C) CONTINUED APPLICABILITY OF PRIOR PROVISIONS.— 35 USC 312 note.

The provisions of chapter 31 of title 35, United States Code, as amended by this paragraph, shall continue to apply to requests for inter partes reexamination that are filed before the effective date set forth in paragraph (2)(A) as if subsection (a) had not been enacted.

(d) POST-GRANT REVIEW.—Part III of title 35, United States Code, is amended by adding at the end the following:

“CHAPTER 32—POST-GRANT REVIEW

“Sec.

“321. Post-grant review.

“322. Petitions.

“323. Preliminary response to petition.

“324. Institution of post-grant review.

“325. Relation to other proceedings or actions.

“326. Conduct of post-grant review.

“327. Settlement.

“328. Decision of the Board.

“329. Appeal.

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“§ 321. Post-grant review

Regulations.

“(a) IN GENERAL.—Subject to the provisions of this chapter, a person who is not the owner of a patent may file with the Office a petition to institute a post-grant review of the patent. The Director shall establish, by regulation, fees to be paid by the person requesting the review, in such amounts as the Director determines to be reasonable, considering the aggregate costs of the post-grant review.

“(b) SCOPE.—A petitioner in a post-grant review may request to cancel as unpatentable 1 or more claims of a patent on any ground that could be raised under paragraph (2) or (3) of section 282(b) (relating to invalidity of the patent or any claim).

“(c) FILING DEADLINE.—A petition for a post-grant review may only be filed not later than the date that is 9 months after the date of the grant of the patent or of the issuance of a reissue patent (as the case may be).

“§ 322. Petitions

“(a) REQUIREMENTS OF PETITION.—A petition filed under section 321 may be considered only if—

“(1) the petition is accompanied by payment of the fee established by the Director under section 321;

“(2) the petition identifies all real parties in interest;

“(3) the petition identifies, in writing and with particularity, each claim challenged, the grounds on which the challenge to each claim is based, and the evidence that supports the grounds for the challenge to each claim, including—

“(A) copies of patents and printed publications that the petitioner relies upon in support of the petition; and

“(B) affidavits or declarations of supporting evidence and opinions, if the petitioner relies on other factual evidence or on expert opinions;

“(4) the petition provides such other information as the Director may require by regulation; and

“(5) the petitioner provides copies of any of the documents required under paragraphs (2), (3), and (4) to the patent owner or, if applicable, the designated representative of the patent owner.

“(b) PUBLIC AVAILABILITY.—As soon as practicable after the receipt of a petition under section 321, the Director shall make the petition available to the public.

“§ 323. Preliminary response to petition

“If a post-grant review petition is filed under section 321, the patent owner shall have the right to file a preliminary response to the petition, within a time period set by the Director, that sets forth reasons why no post-grant review should be instituted based upon the failure of the petition to meet any requirement of this chapter.

“§ 324. Institution of post-grant review

“(a) THRESHOLD.—The Director may not authorize a post-grant review to be instituted unless the Director determines that the information presented in the petition filed under section 321, if such information is not rebutted, would demonstrate that it is more likely than not that at least 1 of the claims challenged in the petition is unpatentable.

“(b) ADDITIONAL GROUNDS.—The determination required under subsection (a) may also be satisfied by a showing that the petition raises a novel or unsettled legal question that is important to other patents or patent applications.

“(c) TIMING.—The Director shall determine whether to institute a post-grant review under this chapter pursuant to a petition filed under section 321 within 3 months after—

“(1) receiving a preliminary response to the petition under section 323; or

“(2) if no such preliminary response is filed, the last date on which such response may be filed.

“(d) NOTICE.—The Director shall notify the petitioner and patent owner, in writing, of the Director’s determination under subsection (a) or (b), and shall make such notice available to the public as soon as is practicable. Such notice shall include the date on which the review shall commence.

“(e) NO APPEAL.—The determination by the Director whether to institute a post-grant review under this section shall be final and nonappealable.

“§ 325. Relation to other proceedings or actions

“(a) INFRINGER’S CIVIL ACTION.—

“(1) POST-GRANT REVIEW BARRED BY CIVIL ACTION.—A post-grant review may not be instituted under this chapter if, before the date on which the petition for such a review is filed, the petitioner or real party in interest filed a civil action challenging the validity of a claim of the patent.

“(2) STAY OF CIVIL ACTION.—If the petitioner or real party in interest files a civil action challenging the validity of a claim of the patent on or after the date on which the petitioner files a petition for post-grant review of the patent, that civil action shall be automatically stayed until either—

“(A) the patent owner moves the court to lift the stay;

“(B) the patent owner files a civil action or counterclaim alleging that the petitioner or real party in interest has infringed the patent; or

“(C) the petitioner or real party in interest moves the court to dismiss the civil action.

“(3) TREATMENT OF COUNTERCLAIM.—A counterclaim challenging the validity of a claim of a patent does not constitute a civil action challenging the validity of a claim of a patent for purposes of this subsection.

“(b) PRELIMINARY INJUNCTIONS.—If a civil action alleging infringement of a patent is filed within 3 months after the date on which the patent is granted, the court may not stay its consideration of the patent owner’s motion for a preliminary injunction against infringement of the patent on the basis that a petition for post-grant review has been filed under this chapter or that such a post-grant review has been instituted under this chapter.

“(c) JOINDER.—If more than 1 petition for a post-grant review under this chapter is properly filed against the same patent and the Director determines that more than 1 of these petitions warrants the institution of a post-grant review under section 324, the Director may consolidate such reviews into a single post-grant review.

“(d) MULTIPLE PROCEEDINGS.—Notwithstanding sections 135(a), 251, and 252, and chapter 30, during the pendency of any post-

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grant review under this chapter, if another proceeding or matter involving the patent is before the Office, the Director may determine the manner in which the post-grant review or other proceeding or matter may proceed, including providing for the stay, transfer, consolidation, or termination of any such matter or proceeding. In determining whether to institute or order a proceeding under this chapter, chapter 30, or chapter 31, the Director may take into account whether, and reject the petition or request because, the same or substantially the same prior art or arguments previously were presented to the Office.

“(e) ESTOPPEL.—

“(1) PROCEEDINGS BEFORE THE OFFICE.—The petitioner in a post-grant review of a claim in a patent under this chapter that results in a final written decision under section 328(a), or the real party in interest or privy of the petitioner, may not request or maintain a proceeding before the Office with respect to that claim on any ground that the petitioner raised or reasonably could have raised during that post-grant review.

“(2) CIVIL ACTIONS AND OTHER PROCEEDINGS.—The petitioner in a post-grant review of a claim in a patent under this chapter that results in a final written decision under section 328(a), or the real party in interest or privy of the petitioner, may not assert either in a civil action arising in whole or in part under section 1338 of title 28 or in a proceeding before the International Trade Commission under section 337 of the Tariff Act of 1930 that the claim is invalid on any ground that the petitioner raised or reasonably could have raised during that post-grant review.

“(f) REISSUE PATENTS.—A post-grant review may not be instituted under this chapter if the petition requests cancellation of a claim in a reissue patent that is identical to or narrower than a claim in the original patent from which the reissue patent was issued, and the time limitations in section 321(c) would bar filing a petition for a post-grant review for such original patent.

“§ 326. Conduct of post-grant review

“(a) REGULATIONS.—The Director shall prescribe regulations—

“(1) providing that the file of any proceeding under this chapter shall be made available to the public, except that any petition or document filed with the intent that it be sealed shall, if accompanied by a motion to seal, be treated as sealed pending the outcome of the ruling on the motion;

“(2) setting forth the standards for the showing of sufficient grounds to institute a review under subsections (a) and (b) of section 324;

“(3) establishing procedures for the submission of supplemental information after the petition is filed;

“(4) establishing and governing a post-grant review under this chapter and the relationship of such review to other proceedings under this title;

“(5) setting forth standards and procedures for discovery of relevant evidence, including that such discovery shall be limited to evidence directly related to factual assertions advanced by either party in the proceeding;

“(6) prescribing sanctions for abuse of discovery, abuse of process, or any other improper use of the proceeding, such

as to harass or to cause unnecessary delay or an unnecessary increase in the cost of the proceeding;

“(7) providing for protective orders governing the exchange and submission of confidential information;

“(8) providing for the filing by the patent owner of a response to the petition under section 323 after a post-grant review has been instituted, and requiring that the patent owner file with such response, through affidavits or declarations, any additional factual evidence and expert opinions on which the patent owner relies in support of the response;

“(9) setting forth standards and procedures for allowing the patent owner to move to amend the patent under subsection (d) to cancel a challenged claim or propose a reasonable number of substitute claims, and ensuring that any information submitted by the patent owner in support of any amendment entered under subsection (d) is made available to the public as part of the prosecution history of the patent;

“(10) providing either party with the right to an oral hearing as part of the proceeding;

“(11) requiring that the final determination in any post-grant review be issued not later than 1 year after the date on which the Director notices the institution of a proceeding under this chapter, except that the Director may, for good cause shown, extend the 1-year period by not more than 6 months, and may adjust the time periods in this paragraph in the case of joinder under section 325(c); and

“(12) providing the petitioner with at least 1 opportunity to file written comments within a time period established by the Director.

“(b) CONSIDERATIONS.—In prescribing regulations under this section, the Director shall consider the effect of any such regulation on the economy, the integrity of the patent system, the efficient administration of the Office, and the ability of the Office to timely complete proceedings instituted under this chapter.

“(c) PATENT TRIAL AND APPEAL BOARD.—The Patent Trial and Appeal Board shall, in accordance with section 6, conduct each post-grant review instituted under this chapter.

“(d) AMENDMENT OF THE PATENT.—

“(1) IN GENERAL.—During a post-grant review instituted under this chapter, the patent owner may file 1 motion to amend the patent in 1 or more of the following ways:

“(A) Cancel any challenged patent claim.

“(B) For each challenged claim, propose a reasonable number of substitute claims.

“(2) ADDITIONAL MOTIONS.—Additional motions to amend may be permitted upon the joint request of the petitioner and the patent owner to materially advance the settlement of a proceeding under section 327, or upon the request of the patent owner for good cause shown.

“(3) SCOPE OF CLAIMS.—An amendment under this subsection may not enlarge the scope of the claims of the patent or introduce new matter.

“(e) EVIDENTIARY STANDARDS.—In a post-grant review instituted under this chapter, the petitioner shall have the burden of proving a proposition of unpatentability by a preponderance of the evidence.

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“§ 327. Settlement

“(a) IN GENERAL.—A post-grant review instituted under this chapter shall be terminated with respect to any petitioner upon the joint request of the petitioner and the patent owner, unless the Office has decided the merits of the proceeding before the request for termination is filed. If the post-grant review is terminated with respect to a petitioner under this section, no estoppel under section 325(e) shall attach to the petitioner, or to the real party in interest or privy of the petitioner, on the basis of that petitioner’s institution of that post-grant review. If no petitioner remains in the post-grant review, the Office may terminate the post-grant review or proceed to a final written decision under section 328(a).

Confidentiality.

“(b) AGREEMENTS IN WRITING.—Any agreement or understanding between the patent owner and a petitioner, including any collateral agreements referred to in such agreement or understanding, made in connection with, or in contemplation of, the termination of a post-grant review under this section shall be in writing, and a true copy of such agreement or understanding shall be filed in the Office before the termination of the post-grant review as between the parties. At the request of a party to the proceeding, the agreement or understanding shall be treated as business confidential information, shall be kept separate from the file of the involved patents, and shall be made available only to Federal Government agencies on written request, or to any person on a showing of good cause.

“§ 328. Decision of the Board

“(a) FINAL WRITTEN DECISION.—If a post-grant review is instituted and not dismissed under this chapter, the Patent Trial and Appeal Board shall issue a final written decision with respect to the patentability of any patent claim challenged by the petitioner and any new claim added under section 326(d).

“(b) CERTIFICATE.—If the Patent Trial and Appeal Board issues a final written decision under subsection (a) and the time for appeal has expired or any appeal has terminated, the Director shall issue and publish a certificate canceling any claim of the patent finally determined to be unpatentable, confirming any claim of the patent determined to be patentable, and incorporating in the patent by operation of the certificate any new or amended claim determined to be patentable.

“(c) INTERVENING RIGHTS.—Any proposed amended or new claim determined to be patentable and incorporated into a patent following a post-grant review under this chapter shall have the same effect as that specified in section 252 of this title for reissued patents on the right of any person who made, purchased, or used within the United States, or imported into the United States, anything patented by such proposed amended or new claim, or who made substantial preparation therefor, before the issuance of a certificate under subsection (b).

Public
information.

“(d) DATA ON LENGTH OF REVIEW.—The Office shall make available to the public data describing the length of time between the institution of, and the issuance of a final written decision under subsection (a) for, each post-grant review.

“§ 329. Appeal

“A party dissatisfied with the final written decision of the Patent Trial and Appeal Board under section 328(a) may appeal the decision pursuant to sections 141 through 144. Any party to the post-grant review shall have the right to be a party to the appeal.”.

(e) CONFORMING AMENDMENT.—The table of chapters for part III of title 35, United States Code, is amended by adding at the end the following:

“32. Post-Grant Review 321”.

(f) REGULATIONS AND EFFECTIVE DATE.—

(1) REGULATIONS.—The Director shall, not later than the date that is 1 year after the date of the enactment of this Act, issue regulations to carry out chapter 32 of title 35, United States Code, as added by subsection (d) of this section. 35 USC 321 note.

(2) APPLICABILITY.—

35 USC 321 note.

(A) IN GENERAL.—The amendments made by subsection (d) shall take effect upon the expiration of the 1-year period beginning on the date of the enactment of this Act and, except as provided in section 18 and in paragraph (3), shall apply only to patents described in section 3(n)(1).

(B) LIMITATION.—The Director may impose a limit on the number of post-grant reviews that may be instituted under chapter 32 of title 35, United States Code, during each of the first 4 1-year periods in which the amendments made by subsection (d) are in effect.

(3) PENDING INTERFERENCES.—

35 USC 321 note.

(A) PROCEDURES IN GENERAL.—The Director shall determine, and include in the regulations issued under paragraph (1), the procedures under which an interference commenced before the effective date set forth in paragraph (2)(A) is to proceed, including whether such interference—

(i) is to be dismissed without prejudice to the filing of a petition for a post-grant review under chapter 32 of title 35, United States Code; or

(ii) is to proceed as if this Act had not been enacted.

(B) PROCEEDINGS BY PATENT TRIAL AND APPEAL BOARD.—For purposes of an interference that is commenced before the effective date set forth in paragraph (2)(A), the Director may deem the Patent Trial and Appeal Board to be the Board of Patent Appeals and Interferences, and may allow the Patent Trial and Appeal Board to conduct any further proceedings in that interference.

(C) APPEALS.—The authorization to appeal or have remedy from derivation proceedings in sections 141(d) and 146 of title 35, United States Code, as amended by this Act, and the jurisdiction to entertain appeals from derivation proceedings in section 1295(a)(4)(A) of title 28, United States Code, as amended by this Act, shall be deemed to extend to any final decision in an interference that is commenced before the effective date set forth in paragraph (2)(A) of this subsection and that is not dismissed pursuant to this paragraph.

(g) CITATION OF PRIOR ART AND WRITTEN STATEMENTS.—

(1) IN GENERAL.—Section 301 of title 35, United States Code, is amended to read as follows:

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“§ 301. Citation of prior art and written statements

“(a) IN GENERAL.—Any person at any time may cite to the Office in writing—

“(1) prior art consisting of patents or printed publications which that person believes to have a bearing on the patentability of any claim of a particular patent; or

“(2) statements of the patent owner filed in a proceeding before a Federal court or the Office in which the patent owner took a position on the scope of any claim of a particular patent.

“(b) OFFICIAL FILE.—If the person citing prior art or written statements pursuant to subsection (a) explains in writing the pertinence and manner of applying the prior art or written statements to at least 1 claim of the patent, the citation of the prior art or written statements and the explanation thereof shall become a part of the official file of the patent.

“(c) ADDITIONAL INFORMATION.—A party that submits a written statement pursuant to subsection (a)(2) shall include any other documents, pleadings, or evidence from the proceeding in which the statement was filed that addresses the written statement.

“(d) LIMITATIONS.—A written statement submitted pursuant to subsection (a)(2), and additional information submitted pursuant to subsection (c), shall not be considered by the Office for any purpose other than to determine the proper meaning of a patent claim in a proceeding that is ordered or instituted pursuant to section 304, 314, or 324. If any such written statement or additional information is subject to an applicable protective order, such statement or information shall be redacted to exclude information that is subject to that order.

“(e) CONFIDENTIALITY.—Upon the written request of the person citing prior art or written statements pursuant to subsection (a), that person’s identity shall be excluded from the patent file and kept confidential.”.

(2) CONFORMING AMENDMENT.—The item relating to section 301 in the table of sections for chapter 30 of title 35, United States Code, is amended to read as follows:

“301. Citation of prior art and written statements.”.

35 USC 301 note.

(3) EFFECTIVE DATE.—The amendments made by this subsection shall take effect upon the expiration of the 1-year period beginning on the date of the enactment of this Act and shall apply to any patent issued before, on, or after that effective date.

(h) REEXAMINATION.—

(1) DETERMINATION BY DIRECTOR.—

(A) IN GENERAL.—Section 303(a) of title 35, United States Code, is amended by striking “section 301 of this title” and inserting “section 301 or 302”.

Applicability.
35 USC 303 note.

(B) EFFECTIVE DATE.—The amendment made by this paragraph shall take effect upon the expiration of the 1-year period beginning on the date of the enactment of this Act and shall apply to any patent issued before, on, or after that effective date.

(2) APPEAL.—

(A) IN GENERAL.—Section 306 of title 35, United States Code, is amended by striking “145” and inserting “144”.

Applicability.
35 USC 306 note.

(B) EFFECTIVE DATE.—The amendment made by this paragraph shall take effect on the date of the enactment

of this Act and shall apply to any appeal of a reexamination before the Board of Patent Appeals and Interferences or the Patent Trial and Appeal Board that is pending on, or brought on or after, the date of the enactment of this Act.

SEC. 7. PATENT TRIAL AND APPEAL BOARD.

(a) COMPOSITION AND DUTIES.—

(1) IN GENERAL.—Section 6 of title 35, United States Code, is amended to read as follows:

“§ 6. Patent Trial and Appeal Board

“(a) IN GENERAL.—There shall be in the Office a Patent Trial and Appeal Board. The Director, the Deputy Director, the Commissioner for Patents, the Commissioner for Trademarks, and the administrative patent judges shall constitute the Patent Trial and Appeal Board. The administrative patent judges shall be persons of competent legal knowledge and scientific ability who are appointed by the Secretary, in consultation with the Director. Any reference in any Federal law, Executive order, rule, regulation, or delegation of authority, or any document of or pertaining to the Board of Patent Appeals and Interferences is deemed to refer to the Patent Trial and Appeal Board.

Establishment.

“(b) DUTIES.—The Patent Trial and Appeal Board shall—

“(1) on written appeal of an applicant, review adverse decisions of examiners upon applications for patents pursuant to section 134(a);

“(2) review appeals of reexaminations pursuant to section 134(b);

“(3) conduct derivation proceedings pursuant to section 135; and

“(4) conduct inter partes reviews and post-grant reviews pursuant to chapters 31 and 32.

“(c) 3-MEMBER PANELS.—Each appeal, derivation proceeding, post-grant review, and inter partes review shall be heard by at least 3 members of the Patent Trial and Appeal Board, who shall be designated by the Director. Only the Patent Trial and Appeal Board may grant rehearings.

“(d) TREATMENT OF PRIOR APPOINTMENTS.—The Secretary of Commerce may, in the Secretary’s discretion, deem the appointment of an administrative patent judge who, before the date of the enactment of this subsection, held office pursuant to an appointment by the Director to take effect on the date on which the Director initially appointed the administrative patent judge. It shall be a defense to a challenge to the appointment of an administrative patent judge on the basis of the judge’s having been originally appointed by the Director that the administrative patent judge so appointed was acting as a de facto officer.”.

(2) CONFORMING AMENDMENT.—The item relating to section 6 in the table of sections for chapter 1 of title 35, United States Code, is amended to read as follows:

“6. Patent Trial and Appeal Board.”.

(b) ADMINISTRATIVE APPEALS.—Section 134 of title 35, United States Code, is amended—

(1) in subsection (b), by striking “any reexamination proceeding” and inserting “a reexamination”; and

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(2) by striking subsection (c).

(c) CIRCUIT APPEALS.—

(1) IN GENERAL.—Section 141 of title 35, United States Code, is amended to read as follows:

“§ 141. Appeal to Court of Appeals for the Federal Circuit

“(a) EXAMINATIONS.—An applicant who is dissatisfied with the final decision in an appeal to the Patent Trial and Appeal Board under section 134(a) may appeal the Board’s decision to the United States Court of Appeals for the Federal Circuit. By filing such an appeal, the applicant waives his or her right to proceed under section 145.

“(b) REEXAMINATIONS.—A patent owner who is dissatisfied with the final decision in an appeal of a reexamination to the Patent Trial and Appeal Board under section 134(b) may appeal the Board’s decision only to the United States Court of Appeals for the Federal Circuit.

“(c) POST-GRANT AND INTER PARTES REVIEWS.—A party to an inter partes review or a post-grant review who is dissatisfied with the final written decision of the Patent Trial and Appeal Board under section 318(a) or 328(a) (as the case may be) may appeal the Board’s decision only to the United States Court of Appeals for the Federal Circuit.

Deadlines.
Notices.

“(d) DERIVATION PROCEEDINGS.—A party to a derivation proceeding who is dissatisfied with the final decision of the Patent Trial and Appeal Board in the proceeding may appeal the decision to the United States Court of Appeals for the Federal Circuit, but such appeal shall be dismissed if any adverse party to such derivation proceeding, within 20 days after the appellant has filed notice of appeal in accordance with section 142, files notice with the Director that the party elects to have all further proceedings conducted as provided in section 146. If the appellant does not, within 30 days after the filing of such notice by the adverse party, file a civil action under section 146, the Board’s decision shall govern the further proceedings in the case.”.

(2) JURISDICTION.—Section 1295(a)(4)(A) of title 28, United States Code, is amended to read as follows:

“(A) the Patent Trial and Appeal Board of the United States Patent and Trademark Office with respect to a patent application, derivation proceeding, reexamination, post-grant review, or inter partes review under title 35, at the instance of a party who exercised that party’s right to participate in the applicable proceeding before or appeal to the Board, except that an applicant or a party to a derivation proceeding may also have remedy by civil action pursuant to section 145 or 146 of title 35; an appeal under this subparagraph of a decision of the Board with respect to an application or derivation proceeding shall waive the right of such applicant or party to proceed under section 145 or 146 of title 35;”.

(3) PROCEEDINGS ON APPEAL.—Section 143 of title 35, United States Code, is amended—

(A) by striking the third sentence and inserting the following: “In an ex parte case, the Director shall submit to the court in writing the grounds for the decision of the Patent and Trademark Office, addressing all of the issues raised in the appeal. The Director shall have the

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right to intervene in an appeal from a decision entered by the Patent Trial and Appeal Board in a derivation proceeding under section 135 or in an inter partes or post-grant review under chapter 31 or 32.”; and

(B) by striking the last sentence.

(d) CONFORMING AMENDMENTS.—

(1) ATOMIC ENERGY ACT OF 1954.—Section 152 of the Atomic Energy Act of 1954 (42 U.S.C. 2182) is amended in the third undesignated paragraph—

(A) by striking “Board of Patent Appeals and Interferences” each place it appears and inserting “Patent Trial and Appeal Board”; and

(B) by inserting “and derivation” after “established for interference”.

(2) TITLE 51.—Section 20135 of title 51, United States Code, is amended—

(A) in subsections (e) and (f), by striking “Board of Patent Appeals and Interferences” each place it appears and inserting “Patent Trial and Appeal Board”; and

(B) in subsection (e), by inserting “and derivation” after “established for interference”.

(e) EFFECTIVE DATE.—The amendments made by this section shall take effect upon the expiration of the 1-year period beginning on the date of the enactment of this Act and shall apply to proceedings commenced on or after that effective date, except that—

35 USC 6 note.

(1) the extension of jurisdiction to the United States Court of Appeals for the Federal Circuit to entertain appeals of decisions of the Patent Trial and Appeal Board in reexaminations under the amendment made by subsection (c)(2) shall be deemed to take effect on the date of the enactment of this Act and shall extend to any decision of the Board of Patent Appeals and Interferences with respect to a reexamination that is entered before, on, or after the date of the enactment of this Act;

(2) the provisions of sections 6, 134, and 141 of title 35, United States Code, as in effect on the day before the effective date of the amendments made by this section shall continue to apply to inter partes reexaminations that are requested under section 311 of such title before such effective date;

(3) the Patent Trial and Appeal Board may be deemed to be the Board of Patent Appeals and Interferences for purposes of appeals of inter partes reexaminations that are requested under section 311 of title 35, United States Code, before the effective date of the amendments made by this section; and

(4) the Director’s right under the fourth sentence of section 143 of title 35, United States Code, as amended by subsection (c)(3) of this section, to intervene in an appeal from a decision entered by the Patent Trial and Appeal Board shall be deemed to extend to inter partes reexaminations that are requested under section 311 of such title before the effective date of the amendments made by this section.

SEC. 8. PREISSUANCE SUBMISSIONS BY THIRD PARTIES.

(a) IN GENERAL.—Section 122 of title 35, United States Code, is amended by adding at the end the following:

“(e) PREISSUANCE SUBMISSIONS BY THIRD PARTIES.—

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“(1) IN GENERAL.—Any third party may submit for consideration and inclusion in the record of a patent application, any patent, published patent application, or other printed publication of potential relevance to the examination of the application, if such submission is made in writing before the earlier of—

“(A) the date a notice of allowance under section 151 is given or mailed in the application for patent; or

“(B) the later of—

“(i) 6 months after the date on which the application for patent is first published under section 122 by the Office, or

“(ii) the date of the first rejection under section 132 of any claim by the examiner during the examination of the application for patent.

“(2) OTHER REQUIREMENTS.—Any submission under paragraph (1) shall—

“(A) set forth a concise description of the asserted relevance of each submitted document;

“(B) be accompanied by such fee as the Director may prescribe; and

“(C) include a statement by the person making such submission affirming that the submission was made in compliance with this section.”.

Applicability.
35 USC 122 note.

(b) EFFECTIVE DATE.—The amendments made by this section shall take effect upon the expiration of the 1-year period beginning on the date of the enactment of this Act and shall apply to any patent application filed before, on, or after that effective date.

SEC. 9. VENUE.

(a) TECHNICAL AMENDMENTS RELATING TO VENUE.—Sections 32, 145, 146, 154(b)(4)(A), and 293 of title 35, United States Code, and section 21(b)(4) of the Trademark Act of 1946 (15 U.S.C. 1071(b)(4)), are each amended by striking “United States District Court for the District of Columbia” each place that term appears and inserting “United States District Court for the Eastern District of Virginia”.

Applicability.
35 USC 1071
note.

(b) EFFECTIVE DATE.—The amendments made by this section shall take effect on the date of the enactment of this Act and shall apply to any civil action commenced on or after that date.

35 USC 41 note.

SEC. 10. FEE SETTING AUTHORITY.

(a) FEE SETTING.—

(1) IN GENERAL.—The Director may set or adjust by rule any fee established, authorized, or charged under title 35, United States Code, or the Trademark Act of 1946 (15 U.S.C. 1051 et seq.), for any services performed by or materials furnished by, the Office, subject to paragraph (2).

(2) FEES TO RECOVER COSTS.—Fees may be set or adjusted under paragraph (1) only to recover the aggregate estimated costs to the Office for processing, activities, services, and materials relating to patents (in the case of patent fees) and trademarks (in the case of trademark fees), including administrative costs of the Office with respect to such patent or trademark fees (as the case may be).

(b) SMALL AND MICRO ENTITIES.—The fees set or adjusted under subsection (a) for filing, searching, examining, issuing, appealing, and maintaining patent applications and patents shall be reduced by 50 percent with respect to the application of such fees to any

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small entity that qualifies for reduced fees under section 41(h)(1) of title 35, United States Code, and shall be reduced by 75 percent with respect to the application of such fees to any micro entity as defined in section 123 of that title (as added by subsection (g) of this section).

(c) REDUCTION OF FEES IN CERTAIN FISCAL YEARS.—In each fiscal year, the Director—

(1) shall consult with the Patent Public Advisory Committee and the Trademark Public Advisory Committee on the advisability of reducing any fees described in subsection (a); and Consultation.

(2) after the consultation required under paragraph (1), may reduce such fees.

(d) ROLE OF THE PUBLIC ADVISORY COMMITTEE.—The Director shall—

(1) not less than 45 days before publishing any proposed fee under subsection (a) in the Federal Register, submit the proposed fee to the Patent Public Advisory Committee or the Trademark Public Advisory Committee, or both, as appropriate; Deadline.

(2)(A) provide the relevant advisory committee described in paragraph (1) a 30-day period following the submission of any proposed fee, in which to deliberate, consider, and comment on such proposal; Time period.

(B) require that, during that 30-day period, the relevant advisory committee hold a public hearing relating to such proposal; and Time period.

(C) assist the relevant advisory committee in carrying out that public hearing, including by offering the use of the resources of the Office to notify and promote the hearing to the public and interested stakeholders;

(3) require the relevant advisory committee to make available to the public a written report setting forth in detail the comments, advice, and recommendations of the committee regarding the proposed fee; and

(4) consider and analyze any comments, advice, or recommendations received from the relevant advisory committee before setting or adjusting (as the case may be) the fee.

(e) PUBLICATION IN THE FEDERAL REGISTER.—

(1) PUBLICATION AND RATIONALE.—The Director shall—

(A) publish any proposed fee change under this section in the Federal Register;

(B) include, in such publication, the specific rationale and purpose for the proposal, including the possible expectations or benefits resulting from the proposed change; and

(C) notify, through the Chair and Ranking Member of the Committees on the Judiciary of the Senate and the House of Representatives, the Congress of the proposed change not later than the date on which the proposed change is published under subparagraph (A). Notification.
Deadline.

(2) PUBLIC COMMENT PERIOD.—The Director shall, in the publication under paragraph (1), provide the public a period of not less than 45 days in which to submit comments on the proposed change in fees.

(3) PUBLICATION OF FINAL RULE.—The final rule setting or adjusting a fee under this section shall be published in

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the Federal Register and in the Official Gazette of the Patent and Trademark Office.

(4) CONGRESSIONAL COMMENT PERIOD.—A fee set or adjusted under subsection (a) may not become effective—

(A) before the end of the 45-day period beginning on the day after the date on which the Director publishes the final rule adjusting or setting the fee under paragraph (3); or

(B) if a law is enacted disapproving such fee.

(5) RULE OF CONSTRUCTION.—Rules prescribed under this section shall not diminish—

(A) the rights of an applicant for a patent under title 35, United States Code, or for a mark under the Trademark Act of 1946; or

(B) any rights under a ratified treaty.

(f) RETENTION OF AUTHORITY.—The Director retains the authority under subsection (a) to set or adjust fees only during such period as the Patent and Trademark Office remains an agency within the Department of Commerce.

(g) MICRO ENTITY DEFINED.—

(1) IN GENERAL.—Chapter 11 of title 35, United States Code, is amended by adding at the end the following new section:

“§ 123. Micro entity defined

“(a) IN GENERAL.—For purposes of this title, the term ‘micro entity’ means an applicant who makes a certification that the applicant—

“(1) qualifies as a small entity, as defined in regulations issued by the Director;

“(2) has not been named as an inventor on more than 4 previously filed patent applications, other than applications filed in another country, provisional applications under section 111(b), or international applications filed under the treaty defined in section 351(a) for which the basic national fee under section 41(a) was not paid;

“(3) did not, in the calendar year preceding the calendar year in which the applicable fee is being paid, have a gross income, as defined in section 61(a) of the Internal Revenue Code of 1986, exceeding 3 times the median household income for that preceding calendar year, as most recently reported by the Bureau of the Census; and

“(4) has not assigned, granted, or conveyed, and is not under an obligation by contract or law to assign, grant, or convey, a license or other ownership interest in the application concerned to an entity that, in the calendar year preceding the calendar year in which the applicable fee is being paid, had a gross income, as defined in section 61(a) of the Internal Revenue Code of 1986, exceeding 3 times the median household income for that preceding calendar year, as most recently reported by the Bureau of the Census.

“(b) APPLICATIONS RESULTING FROM PRIOR EMPLOYMENT.—An applicant is not considered to be named on a previously filed application for purposes of subsection (a)(2) if the applicant has assigned, or is under an obligation by contract or law to assign, all ownership rights in the application as the result of the applicant’s previous employment.

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“(c) FOREIGN CURRENCY EXCHANGE RATE.—If an applicant’s or entity’s gross income in the preceding calendar year is not in United States dollars, the average currency exchange rate, as reported by the Internal Revenue Service, during that calendar year shall be used to determine whether the applicant’s or entity’s gross income exceeds the threshold specified in paragraphs (3) or (4) of subsection (a).

“(d) INSTITUTIONS OF HIGHER EDUCATION.—For purposes of this section, a micro entity shall include an applicant who certifies that—

“(1) the applicant’s employer, from which the applicant obtains the majority of the applicant’s income, is an institution of higher education as defined in section 101(a) of the Higher Education Act of 1965 (20 U.S.C. 1001(a)); or

“(2) the applicant has assigned, granted, conveyed, or is under an obligation by contract or law, to assign, grant, or convey, a license or other ownership interest in the particular applications to such an institution of higher education.

“(e) DIRECTOR’S AUTHORITY.—In addition to the limits imposed by this section, the Director may, in the Director’s discretion, impose income limits, annual filing limits, or other limits on who may qualify as a micro entity pursuant to this section if the Director determines that such additional limits are reasonably necessary to avoid an undue impact on other patent applicants or owners or are otherwise reasonably necessary and appropriate. At least 3 months before any limits proposed to be imposed pursuant to this subsection take effect, the Director shall inform the Committee on the Judiciary of the House of Representatives and the Committee on the Judiciary of the Senate of any such proposed limits.”.

Deadline.
Notification.

(2) CONFORMING AMENDMENT.—Chapter 11 of title 35, United States Code, is amended by adding at the end the following new item:

“123. Micro entity defined.”.

(h) ELECTRONIC FILING INCENTIVE.—

(1) IN GENERAL.—Notwithstanding any other provision of this section, an additional fee of \$400 shall be established for each application for an original patent, except for a design, plant, or provisional application, that is not filed by electronic means as prescribed by the Director. The fee established by this subsection shall be reduced by 50 percent for small entities that qualify for reduced fees under section 41(h)(1) of title 35, United States Code. All fees paid under this subsection shall be deposited in the Treasury as an offsetting receipt that shall not be available for obligation or expenditure.

(2) EFFECTIVE DATE.—This subsection shall take effect upon the expiration of the 60-day period beginning on the date of the enactment of this Act.

(i) EFFECTIVE DATE; SUNSET.—

(1) EFFECTIVE DATE.—Except as provided in subsection (h), this section and the amendments made by this section shall take effect on the date of the enactment of this Act.

(2) SUNSET.—The authority of the Director to set or adjust any fee under subsection (a) shall terminate upon the expiration of the 7-year period beginning on the date of the enactment of this Act.

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(3) PRIOR REGULATIONS NOT AFFECTED.—The termination of authority under this subsection shall not affect any regulations issued under this section before the effective date of such termination or any rulemaking proceeding for the issuance of regulations under this section that is pending on such date.

SEC. 11. FEES FOR PATENT SERVICES.

(a) GENERAL PATENT SERVICES.—Subsections (a) and (b) of section 41 of title 35, United States Code, are amended to read as follows:

“(a) GENERAL FEES.—The Director shall charge the following fees:

“(1) FILING AND BASIC NATIONAL FEES.—

“(A) On filing each application for an original patent, except for design, plant, or provisional applications, \$330.

“(B) On filing each application for an original design patent, \$220.

“(C) On filing each application for an original plant patent, \$220.

“(D) On filing each provisional application for an original patent, \$220.

“(E) On filing each application for the reissue of a patent, \$330.

“(F) The basic national fee for each international application filed under the treaty defined in section 351(a) entering the national stage under section 371, \$330.

“(G) In addition, excluding any sequence listing or computer program listing filed in an electronic medium as prescribed by the Director, for any application the specification and drawings of which exceed 100 sheets of paper (or equivalent as prescribed by the Director if filed in an electronic medium), \$270 for each additional 50 sheets of paper (or equivalent as prescribed by the Director if filed in an electronic medium) or fraction thereof.

“(2) EXCESS CLAIMS FEES.—

“(A) IN GENERAL.—In addition to the fee specified in paragraph (1)—

“(i) on filing or on presentation at any other time, \$220 for each claim in independent form in excess of 3;

“(ii) on filing or on presentation at any other time, \$52 for each claim (whether dependent or independent) in excess of 20; and

“(iii) for each application containing a multiple dependent claim, \$390.

“(B) MULTIPLE DEPENDENT CLAIMS.—For the purpose of computing fees under subparagraph (A), a multiple dependent claim referred to in section 112 or any claim depending therefrom shall be considered as separate dependent claims in accordance with the number of claims to which reference is made.

“(C) REFUNDS; ERRORS IN PAYMENT.—The Director may by regulation provide for a refund of any part of the fee specified in subparagraph (A) for any claim that is canceled before an examination on the merits, as prescribed by the Director, has been made of the application under section 131. Errors in payment of the additional fees under

this paragraph may be rectified in accordance with regulations prescribed by the Director.

“(3) EXAMINATION FEES.—

“(A) IN GENERAL.—

“(i) For examination of each application for an original patent, except for design, plant, provisional, or international applications, \$220.

“(ii) For examination of each application for an original design patent, \$140.

“(iii) For examination of each application for an original plant patent, \$170.

“(iv) For examination of the national stage of each international application, \$220.

“(v) For examination of each application for the reissue of a patent, \$650.

“(B) APPLICABILITY OF OTHER FEE PROVISIONS.—The provisions of paragraphs (3) and (4) of section 111(a) relating to the payment of the fee for filing the application shall apply to the payment of the fee specified in subparagraph (A) with respect to an application filed under section 111(a). The provisions of section 371(d) relating to the payment of the national fee shall apply to the payment of the fee specified in subparagraph (A) with respect to an international application.

“(4) ISSUE FEES.—

“(A) For issuing each original patent, except for design or plant patents, \$1,510.

“(B) For issuing each original design patent, \$860.

“(C) For issuing each original plant patent, \$1,190.

“(D) For issuing each reissue patent, \$1,510.

“(5) DISCLAIMER FEE.—On filing each disclaimer, \$140.

“(6) APPEAL FEES.—

“(A) On filing an appeal from the examiner to the Patent Trial and Appeal Board, \$540.

“(B) In addition, on filing a brief in support of the appeal, \$540, and on requesting an oral hearing in the appeal before the Patent Trial and Appeal Board, \$1,080.

“(7) REVIVAL FEES.—On filing each petition for the revival of an unintentionally abandoned application for a patent, for the unintentionally delayed payment of the fee for issuing each patent, or for an unintentionally delayed response by the patent owner in any reexamination proceeding, \$1,620, unless the petition is filed under section 133 or 151, in which case the fee shall be \$540.

“(8) EXTENSION FEES.—For petitions for 1-month extensions of time to take actions required by the Director in an application—

“(A) on filing a first petition, \$130;

“(B) on filing a second petition, \$360; and

“(C) on filing a third or subsequent petition, \$620.

“(b) MAINTENANCE FEES.—

“(1) IN GENERAL.—The Director shall charge the following fees for maintaining in force all patents based on applications filed on or after December 12, 1980:

“(A) Three years and 6 months after grant, \$980.

“(B) Seven years and 6 months after grant, \$2,480.

“(C) Eleven years and 6 months after grant, \$4,110.

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Expiration date.

“(2) GRACE PERIOD; SURCHARGE.—Unless payment of the applicable maintenance fee under paragraph (1) is received in the Office on or before the date the fee is due or within a grace period of 6 months thereafter, the patent shall expire as of the end of such grace period. The Director may require the payment of a surcharge as a condition of accepting within such 6-month grace period the payment of an applicable maintenance fee.

“(3) NO MAINTENANCE FEE FOR DESIGN OR PLANT PATENT.—No fee may be established for maintaining a design or plant patent in force.”.

(b) DELAYS IN PAYMENT.—Subsection (c) of section 41 of title 35, United States Code, is amended—

(1) by striking “(c)(1) The Director” and inserting:

“(c) DELAYS IN PAYMENT OF MAINTENANCE FEES.—

“(1) ACCEPTANCE.—The Director”; and

(2) by striking “(2) A patent” and inserting:

“(2) EFFECT ON RIGHTS OF OTHERS.—A patent”.

(c) PATENT SEARCH FEES.—Subsection (d) of section 41 of title 35, United States Code, is amended to read as follows:

“(d) PATENT SEARCH AND OTHER FEES.—

“(1) PATENT SEARCH FEES.—

“(A) IN GENERAL.—The Director shall charge the fees specified under subparagraph (B) for the search of each application for a patent, except for provisional applications. The Director shall adjust the fees charged under this paragraph to ensure that the fees recover an amount not to exceed the estimated average cost to the Office of searching applications for patent by Office personnel.

“(B) SPECIFIC FEES.—The fees referred to in subparagraph (A) are—

“(i) \$540 for each application for an original patent, except for design, plant, provisional, or international applications;

“(ii) \$100 for each application for an original design patent;

“(iii) \$330 for each application for an original plant patent;

“(iv) \$540 for the national stage of each international application; and

“(v) \$540 for each application for the reissue of a patent.

“(C) APPLICABILITY OF OTHER PROVISIONS.—The provisions of paragraphs (3) and (4) of section 111(a) relating to the payment of the fee for filing the application shall apply to the payment of the fee specified in this paragraph with respect to an application filed under section 111(a). The provisions of section 371(d) relating to the payment of the national fee shall apply to the payment of the fee specified in this paragraph with respect to an international application.

Regulations.

“(D) REFUNDS.—The Director may by regulation provide for a refund of any part of the fee specified in this paragraph for any applicant who files a written declaration of express abandonment as prescribed by the Director before an examination has been made of the application under section 131.

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“(2) OTHER FEES.—

“(A) IN GENERAL.—The Director shall establish fees for all other processing, services, or materials relating to patents not specified in this section to recover the estimated average cost to the Office of such processing, services, or materials, except that the Director shall charge the following fees for the following services:

“(i) For recording a document affecting title, \$40 per property.

“(ii) For each photocopy, \$.25 per page.

“(iii) For each black and white copy of a patent, \$3.

“(B) COPIES FOR LIBRARIES.—The yearly fee for providing a library specified in section 12 with uncertified printed copies of the specifications and drawings for all patents in that year shall be \$50.”.

(d) FEES FOR SMALL ENTITIES.—Subsection (h) of section 41 of title 35, United States Code, is amended to read as follows:

“(h) FEES FOR SMALL ENTITIES.—

“(1) REDUCTIONS IN FEES.—Subject to paragraph (3), fees charged under subsections (a), (b), and (d)(1) shall be reduced by 50 percent with respect to their application to any small business concern as defined under section 3 of the Small Business Act, and to any independent inventor or nonprofit organization as defined in regulations issued by the Director.

“(2) SURCHARGES AND OTHER FEES.—With respect to its application to any entity described in paragraph (1), any surcharge or fee charged under subsection (c) or (d) shall not be higher than the surcharge or fee required of any other entity under the same or substantially similar circumstances.

“(3) REDUCTION FOR ELECTRONIC FILING.—The fee charged under subsection (a)(1)(A) shall be reduced by 75 percent with respect to its application to any entity to which paragraph (1) applies, if the application is filed by electronic means as prescribed by the Director.”.

(e) TECHNICAL AMENDMENTS.—Section 41 of title 35, United States Code, is amended—

(1) in subsection (e), in the first sentence, by striking “The Director” and inserting “WAIVER OF FEES; COPIES REGARDING NOTICE.—The Director”;

(2) in subsection (f), by striking “The fees” and inserting “ADJUSTMENT OF FEES.—The fees”;

(3) by repealing subsection (g); and

(4) in subsection (i)—

(A) by striking “(i)(1) The Director” and inserting the following:

“(i) ELECTRONIC PATENT AND TRADEMARK DATA.—

“(1) MAINTENANCE OF COLLECTIONS.—The Director”;

(B) by striking “(2) The Director” and inserting the following:

“(2) AVAILABILITY OF AUTOMATED SEARCH SYSTEMS.—The Director”;

(C) by striking “(3) The Director” and inserting the following:

“(3) ACCESS FEES.—The Director”; and

(D) by striking “(4) The Director” and inserting the following:

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“(4) ANNUAL REPORT TO CONGRESS.—The Director”.

35 USC 41 note. (f) ADJUSTMENT OF TRADEMARK FEES.—Section 802(a) of division B of the Consolidated Appropriations Act, 2005 (Public Law 108-447) is amended—

(1) in the first sentence, by striking “During fiscal years 2005, 2006, and 2007,” and inserting “Until such time as the Director sets or adjusts the fees otherwise,”; and

(2) in the second sentence, by striking “During fiscal years 2005, 2006, and 2007, the” and inserting “The”.

35 USC 41 note. (g) EFFECTIVE DATE, APPLICABILITY, AND TRANSITION PROVISIONS.—Section 803(a) of division B of the Consolidated Appropriations Act, 2005 (Public Law 108-447) is amended by striking “and shall apply only with respect to the remaining portion of fiscal year 2005 and fiscal year 2006”.

35 USC 41 note. (h) PRIORITIZED EXAMINATION FEE.—

(1) IN GENERAL.—

(A) FEE.—

(i) PRIORITIZED EXAMINATION FEE.—A fee of \$4,800 shall be established for filing a request, pursuant to section 2(b)(2)(G) of title 35, United States Code, for prioritized examination of a nonprovisional application for an original utility or plant patent.

(ii) ADDITIONAL FEES.—In addition to the prioritized examination fee under clause (i), the fees due on an application for which prioritized examination is being sought are the filing, search, and examination fees (including any applicable excess claims and application size fees), processing fee, and publication fee for that application.

(B) REGULATIONS; LIMITATIONS.—

(i) REGULATIONS.—The Director may by regulation prescribe conditions for acceptance of a request under subparagraph (A) and a limit on the number of filings for prioritized examination that may be accepted.

(ii) LIMITATION ON CLAIMS.—Until regulations are prescribed under clause (i), no application for which prioritized examination is requested may contain or be amended to contain more than 4 independent claims or more than 30 total claims.

(iii) LIMITATION ON TOTAL NUMBER OF REQUESTS.—The Director may not accept in any fiscal year more than 10,000 requests for prioritization until regulations are prescribed under this subparagraph setting another limit.

(2) REDUCTION IN FEES FOR SMALL ENTITIES.—The Director shall reduce fees for providing prioritized examination of nonprovisional applications for original utility and plant patents by 50 percent for small entities that qualify for reduced fees under section 41(h)(1) of title 35, United States Code.

(3) DEPOSIT OF FEES.—All fees paid under this subsection shall be credited to the United States Patent and Trademark Office Appropriation Account, shall remain available until expended, and may be used only for the purposes specified in section 42(c)(3)(A) of title 35, United States Code.

(4) EFFECTIVE DATE AND TERMINATION.—

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(A) **EFFECTIVE DATE.**—This subsection shall take effect on the date that is 10 days after the date of the enactment of this Act.

(B) **TERMINATION.**—The fee imposed under paragraph (1)(A)(i), and the reduced fee under paragraph (2), shall terminate on the effective date of the setting or adjustment of the fee under paragraph (1)(A)(i) pursuant to the exercise of the authority under section 10 for the first time with respect to that fee.

(i) **APPROPRIATION ACCOUNT TRANSITION FEES.**—

35 USC 41 note.

(1) **SURCHARGE.**—

(A) **IN GENERAL.**—There shall be a surcharge of 15 percent, rounded by standard arithmetic rules, on all fees charged or authorized by subsections (a), (b), and (d)(1) of section 41, and section 132(b), of title 35, United States Code. Any surcharge imposed under this subsection is, and shall be construed to be, separate from and in addition to any other surcharge imposed under this Act or any other provision of law.

(B) **DEPOSIT OF AMOUNTS.**—Amounts collected pursuant to the surcharge imposed under subparagraph (A) shall be credited to the United States Patent and Trademark Appropriation Account, shall remain available until expended, and may be used only for the purposes specified in section 42(c)(3)(A) of title 35, United States Code.

(2) **EFFECTIVE DATE AND TERMINATION OF SURCHARGE.**—

The surcharge provided for in paragraph (1)—

(A) shall take effect on the date that is 10 days after the date of the enactment of this Act; and

(B) shall terminate, with respect to a fee to which paragraph (1)(A) applies, on the effective date of the setting or adjustment of that fee pursuant to the exercise of the authority under section 10 for the first time with respect to that fee.

Applicability.

(j) **EFFECTIVE DATE.**—Except as otherwise provided in this section, this section and the amendments made by this section shall take effect on the date of the enactment of this Act.

35 USC 41 note.

SEC. 12. SUPPLEMENTAL EXAMINATION.

(a) **IN GENERAL.**—Chapter 25 of title 35, United States Code, is amended by adding at the end the following:

“§ 257. Supplemental examinations to consider, reconsider, or correct information

“(a) **REQUEST FOR SUPPLEMENTAL EXAMINATION.**—A patent owner may request supplemental examination of a patent in the Office to consider, reconsider, or correct information believed to be relevant to the patent, in accordance with such requirements as the Director may establish. Within 3 months after the date a request for supplemental examination meeting the requirements of this section is received, the Director shall conduct the supplemental examination and shall conclude such examination by issuing a certificate indicating whether the information presented in the request raises a substantial new question of patentability.

Deadline.
Certificate.

“(b) **REEXAMINATION ORDERED.**—If the certificate issued under subsection (a) indicates that a substantial new question of patentability is raised by 1 or more items of information in the request,

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the Director shall order reexamination of the patent. The reexamination shall be conducted according to procedures established by chapter 30, except that the patent owner shall not have the right to file a statement pursuant to section 304. During the reexamination, the Director shall address each substantial new question of patentability identified during the supplemental examination, notwithstanding the limitations in chapter 30 relating to patents and printed publication or any other provision of such chapter.

“(c) EFFECT.—

“(1) IN GENERAL.—A patent shall not be held unenforceable on the basis of conduct relating to information that had not been considered, was inadequately considered, or was incorrect in a prior examination of the patent if the information was considered, reconsidered, or corrected during a supplemental examination of the patent. The making of a request under subsection (a), or the absence thereof, shall not be relevant to enforceability of the patent under section 282.

“(2) EXCEPTIONS.—

“(A) PRIOR ALLEGATIONS.—Paragraph (1) shall not apply to an allegation pled with particularity in a civil action, or set forth with particularity in a notice received by the patent owner under section 505(j)(2)(B)(iv)(II) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(j)(2)(B)(iv)(II)), before the date of a supplemental examination request under subsection (a) to consider, reconsider, or correct information forming the basis for the allegation.

“(B) PATENT ENFORCEMENT ACTIONS.—In an action brought under section 337(a) of the Tariff Act of 1930 (19 U.S.C. 1337(a)), or section 281 of this title, paragraph (1) shall not apply to any defense raised in the action that is based upon information that was considered, reconsidered, or corrected pursuant to a supplemental examination request under subsection (a), unless the supplemental examination, and any reexamination ordered pursuant to the request, are concluded before the date on which the action is brought.

“(d) FEES AND REGULATIONS.—

“(1) FEES.—The Director shall, by regulation, establish fees for the submission of a request for supplemental examination of a patent, and to consider each item of information submitted in the request. If reexamination is ordered under subsection (b), fees established and applicable to ex parte reexamination proceedings under chapter 30 shall be paid, in addition to fees applicable to supplemental examination.

“(2) REGULATIONS.—The Director shall issue regulations governing the form, content, and other requirements of requests for supplemental examination, and establishing procedures for reviewing information submitted in such requests.

“(e) FRAUD.—If the Director becomes aware, during the course of a supplemental examination or reexamination proceeding ordered under this section, that a material fraud on the Office may have been committed in connection with the patent that is the subject of the supplemental examination, then in addition to any other actions the Director is authorized to take, including the cancellation of any claims found to be invalid under section 307 as a result of a reexamination ordered under this section, the Director shall

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also refer the matter to the Attorney General for such further action as the Attorney General may deem appropriate. Any such referral shall be treated as confidential, shall not be included in the file of the patent, and shall not be disclosed to the public unless the United States charges a person with a criminal offense in connection with such referral.

“(f) RULE OF CONSTRUCTION.—Nothing in this section shall be construed—

“(1) to preclude the imposition of sanctions based upon criminal or antitrust laws (including section 1001(a) of title 18, the first section of the Clayton Act, and section 5 of the Federal Trade Commission Act to the extent that section relates to unfair methods of competition);

“(2) to limit the authority of the Director to investigate issues of possible misconduct and impose sanctions for misconduct in connection with matters or proceedings before the Office; or

“(3) to limit the authority of the Director to issue regulations under chapter 3 relating to sanctions for misconduct by representatives practicing before the Office.”.

(b) CONFORMING AMENDMENT.—The table of sections for chapter 25 of title 35, United States Code, is amended by adding at the end the following new item:

“257. Supplemental examinations to consider, reconsider, or correct information.”.

(c) EFFECTIVE DATE.—The amendments made by this section shall take effect upon the expiration of the 1-year period beginning on the date of the enactment of this Act and shall apply to any patent issued before, on, or after that effective date.

Applicability.
35 USC 257 note.

SEC. 13. FUNDING AGREEMENTS.

(a) IN GENERAL.—Section 202(c)(7)(E)(i) of title 35, United States Code, is amended—

(1) by striking “75 percent” and inserting “15 percent”;

(2) by striking “25 percent” and inserting “85 percent”;

and

(3) by striking “as described above in this clause (D);” and inserting “described above in this clause;”.

(b) EFFECTIVE DATE.—The amendments made by this section shall take effect on the date of the enactment of this Act and shall apply to any patent issued before, on, or after that date.

Applicability.
35 USC 202 note.

SEC. 14. TAX STRATEGIES DEEMED WITHIN THE PRIOR ART.

35 USC 102 note.

(a) IN GENERAL.—For purposes of evaluating an invention under section 102 or 103 of title 35, United States Code, any strategy for reducing, avoiding, or deferring tax liability, whether known or unknown at the time of the invention or application for patent, shall be deemed insufficient to differentiate a claimed invention from the prior art.

(b) DEFINITION.—For purposes of this section, the term “tax liability” refers to any liability for a tax under any Federal, State, or local law, or the law of any foreign jurisdiction, including any statute, rule, regulation, or ordinance that levies, imposes, or assesses such tax liability.

(c) EXCLUSIONS.—This section does not apply to that part of an invention that—

(1) is a method, apparatus, technology, computer program product, or system, that is used solely for preparing a tax

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or information return or other tax filing, including one that records, transmits, transfers, or organizes data related to such filing; or

(2) is a method, apparatus, technology, computer program product, or system used solely for financial management, to the extent that it is severable from any tax strategy or does not limit the use of any tax strategy by any taxpayer or tax advisor.

(d) **RULE OF CONSTRUCTION.**—Nothing in this section shall be construed to imply that other business methods are patentable or that other business method patents are valid.

(e) **EFFECTIVE DATE; APPLICABILITY.**—This section shall take effect on the date of the enactment of this Act and shall apply to any patent application that is pending on, or filed on or after, that date, and to any patent that is issued on or after that date.

SEC. 15. BEST MODE REQUIREMENT.

(a) **IN GENERAL.**—Section 282 of title 35, United States Code, is amended in the second undesignated paragraph by striking paragraph (3) and inserting the following:

“(3) Invalidity of the patent or any claim in suit for failure to comply with—

“(A) any requirement of section 112, except that the failure to disclose the best mode shall not be a basis on which any claim of a patent may be canceled or held invalid or otherwise unenforceable; or

“(B) any requirement of section 251.”.

(b) **CONFORMING AMENDMENT.**—Sections 119(e)(1) and 120 of title 35, United States Code, are each amended by striking “the first paragraph of section 112 of this title” and inserting “section 112(a) (other than the requirement to disclose the best mode)”.

Applicability.
35 USC 119 note.

(c) **EFFECTIVE DATE.**—The amendments made by this section shall take effect upon the date of the enactment of this Act and shall apply to proceedings commenced on or after that date.

SEC. 16. MARKING.

(a) **VIRTUAL MARKING.**—

(1) **IN GENERAL.**—Section 287(a) of title 35, United States Code, is amended by striking “or when,” and inserting “or by fixing thereon the word ‘patent’ or the abbreviation ‘pat.’ together with an address of a posting on the Internet, accessible to the public without charge for accessing the address, that associates the patented article with the number of the patent, or when,”.

Applicability.
35 USC 287 note.

(2) **EFFECTIVE DATE.**—The amendment made by this subsection shall apply to any case that is pending on, or commenced on or after, the date of the enactment of this Act.

(3) **REPORT.**—Not later than the date that is 3 years after the date of the enactment of this Act, the Director shall submit a report to Congress that provides—

(A) an analysis of the effectiveness of “virtual marking”, as provided in the amendment made by paragraph (1) of this subsection, as an alternative to the physical marking of articles;

(B) an analysis of whether such virtual marking has limited or improved the ability of the general public to access information about patents;

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(C) an analysis of the legal issues, if any, that arise from such virtual marking; and

(D) an analysis of the deficiencies, if any, of such virtual marking.

(b) FALSE MARKING.—

(1) CIVIL PENALTY.—Section 292(a) of title 35, United States Code, is amended by adding at the end the following: “Only the United States may sue for the penalty authorized by this subsection.”

(2) CIVIL ACTION FOR DAMAGES.—Subsection (b) of section 292 of title 35, United States Code, is amended to read as follows:

“(b) A person who has suffered a competitive injury as a result of a violation of this section may file a civil action in a district court of the United States for recovery of damages adequate to compensate for the injury.”

(3) EXPIRED PATENTS.—Section 292 of title 35, United States Code, is amended by adding at the end the following:

“(c) The marking of a product, in a manner described in subsection (a), with matter relating to a patent that covered that product but has expired is not a violation of this section.”

(4) EFFECTIVE DATE.—The amendments made by this subsection shall apply to all cases, without exception, that are pending on, or commenced on or after, the date of the enactment of this Act.

Applicability.
35 USC 292 note.

SEC. 17. ADVICE OF COUNSEL.

(a) IN GENERAL.—Chapter 29 of title 35, United States Code, is amended by adding at the end the following:

“§ 298. Advice of counsel

“The failure of an infringer to obtain the advice of counsel with respect to any allegedly infringed patent, or the failure of the infringer to present such advice to the court or jury, may not be used to prove that the accused infringer willfully infringed the patent or that the infringer intended to induce infringement of the patent.”

(b) CONFORMING AMENDMENT.—The table of sections for chapter 29 of title 35, United States Code, is amended by adding at the end the following:

“298. Advice of counsel.”

SEC. 18. TRANSITIONAL PROGRAM FOR COVERED BUSINESS METHOD PATENTS.

35 USC 321 note.

(a) TRANSITIONAL PROGRAM.—

(1) ESTABLISHMENT.—Not later than the date that is 1 year after the date of the enactment of this Act, the Director shall issue regulations establishing and implementing a transitional post-grant review proceeding for review of the validity of covered business method patents. The transitional proceeding implemented pursuant to this subsection shall be regarded as, and shall employ the standards and procedures of, a post-grant review under chapter 32 of title 35, United States Code, subject to the following:

Deadline.
Regulations.

(A) Section 321(c) of title 35, United States Code, and subsections (b), (e)(2), and (f) of section 325 of such title shall not apply to a transitional proceeding.

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(B) A person may not file a petition for a transitional proceeding with respect to a covered business method patent unless the person or the person's real party in interest or privy has been sued for infringement of the patent or has been charged with infringement under that patent.

(C) A petitioner in a transitional proceeding who challenges the validity of 1 or more claims in a covered business method patent on a ground raised under section 102 or 103 of title 35, United States Code, as in effect on the day before the effective date set forth in section 3(n)(1), may support such ground only on the basis of—

(i) prior art that is described by section 102(a) of such title of such title (as in effect on the day before such effective date); or

(ii) prior art that—

(I) discloses the invention more than 1 year before the date of the application for patent in the United States; and

(II) would be described by section 102(a) of such title (as in effect on the day before the effective date set forth in section 3(n)(1)) if the disclosure had been made by another before the invention thereof by the applicant for patent.

(D) The petitioner in a transitional proceeding that results in a final written decision under section 328(a) of title 35, United States Code, with respect to a claim in a covered business method patent, or the petitioner's real party in interest, may not assert, either in a civil action arising in whole or in part under section 1338 of title 28, United States Code, or in a proceeding before the International Trade Commission under section 337 of the Tariff Act of 1930 (19 U.S.C. 1337), that the claim is invalid on any ground that the petitioner raised during that transitional proceeding.

(E) The Director may institute a transitional proceeding only for a patent that is a covered business method patent.

(2) EFFECTIVE DATE.—The regulations issued under paragraph (1) shall take effect upon the expiration of the 1-year period beginning on the date of the enactment of this Act and shall apply to any covered business method patent issued before, on, or after that effective date, except that the regulations shall not apply to a patent described in section 6(f)(2)(A) of this Act during the period in which a petition for post-grant review of that patent would satisfy the requirements of section 321(c) of title 35, United States Code.

(3) SUNSET.—

(A) IN GENERAL.—This subsection, and the regulations issued under this subsection, are repealed effective upon the expiration of the 8-year period beginning on the date that the regulations issued under to paragraph (1) take effect.

(B) APPLICABILITY.—Notwithstanding subparagraph (A), this subsection and the regulations issued under this subsection shall continue to apply, after the date of the

repeal under subparagraph (A), to any petition for a transitional proceeding that is filed before the date of such repeal.

(b) REQUEST FOR STAY.—

(1) IN GENERAL.—If a party seeks a stay of a civil action alleging infringement of a patent under section 281 of title 35, United States Code, relating to a transitional proceeding for that patent, the court shall decide whether to enter a stay based on—

(A) whether a stay, or the denial thereof, will simplify the issues in question and streamline the trial;

(B) whether discovery is complete and whether a trial date has been set;

(C) whether a stay, or the denial thereof, would unduly prejudice the nonmoving party or present a clear tactical advantage for the moving party; and

(D) whether a stay, or the denial thereof, will reduce the burden of litigation on the parties and on the court.

(2) REVIEW.—A party may take an immediate interlocutory appeal from a district court's decision under paragraph (1). The United States Court of Appeals for the Federal Circuit shall review the district court's decision to ensure consistent application of established precedent, and such review may be de novo.

(c) ATM EXEMPTION FOR VENUE PURPOSES.—In an action for infringement under section 281 of title 35, United States Code, of a covered business method patent, an automated teller machine shall not be deemed to be a regular and established place of business for purposes of section 1400(b) of title 28, United States Code.

(d) DEFINITION.—

(1) IN GENERAL.—For purposes of this section, the term “covered business method patent” means a patent that claims a method or corresponding apparatus for performing data processing or other operations used in the practice, administration, or management of a financial product or service, except that the term does not include patents for technological inventions.

(2) REGULATIONS.—To assist in implementing the transitional proceeding authorized by this subsection, the Director shall issue regulations for determining whether a patent is for a technological invention.

(e) RULE OF CONSTRUCTION.—Nothing in this section shall be construed as amending or interpreting categories of patent-eligible subject matter set forth under section 101 of title 35, United States Code.

SEC. 19. JURISDICTION AND PROCEDURAL MATTERS.

(a) STATE COURT JURISDICTION.—Section 1338(a) of title 28, United States Code, is amended by striking the second sentence and inserting the following: “No State court shall have jurisdiction over any claim for relief arising under any Act of Congress relating to patents, plant variety protection, or copyrights. For purposes of this subsection, the term ‘State’ includes any State of the United States, the District of Columbia, the Commonwealth of Puerto Rico, the United States Virgin Islands, American Samoa, Guam, and the Northern Mariana Islands.”.

(b) COURT OF APPEALS FOR THE FEDERAL CIRCUIT.—Section 1295(a)(1) of title 28, United States Code, is amended to read as follows:

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“(1) of an appeal from a final decision of a district court of the United States, the District Court of Guam, the District Court of the Virgin Islands, or the District Court of the Northern Mariana Islands, in any civil action arising under, or in any civil action in which a party has asserted a compulsory counterclaim arising under, any Act of Congress relating to patents or plant variety protection;”.

(c) REMOVAL.—

(1) IN GENERAL.—Chapter 89 of title 28, United States Code, is amended by adding at the end the following new section:

“§ 1454. Patent, plant variety protection, and copyright cases

“(a) IN GENERAL.—A civil action in which any party asserts a claim for relief arising under any Act of Congress relating to patents, plant variety protection, or copyrights may be removed to the district court of the United States for the district and division embracing the place where the action is pending.

“(b) SPECIAL RULES.—The removal of an action under this section shall be made in accordance with section 1446, except that if the removal is based solely on this section—

“(1) the action may be removed by any party; and

“(2) the time limitations contained in section 1446(b) may be extended at any time for cause shown.

“(c) CLARIFICATION OF JURISDICTION IN CERTAIN CASES.—The court to which a civil action is removed under this section is not precluded from hearing and determining any claim in the civil action because the State court from which the civil action is removed did not have jurisdiction over that claim.

“(d) REMAND.—If a civil action is removed solely under this section, the district court—

“(1) shall remand all claims that are neither a basis for removal under subsection (a) nor within the original or supplemental jurisdiction of the district court under any Act of Congress; and

“(2) may, under the circumstances specified in section 1367(c), remand any claims within the supplemental jurisdiction of the district court under section 1367.”.

(2) CONFORMING AMENDMENT.—The table of sections for chapter 89 of title 28, United States Code, is amended by adding at the end the following new item:

“1454. Patent, plant variety protection, and copyright cases.”.

(d) PROCEDURAL MATTERS IN PATENT CASES.—

(1) JOINDER OF PARTIES AND STAY OF ACTIONS.—Chapter 29 of title 35, United States Code, as amended by this Act, is further amended by adding at the end the following new section:

“§ 299. Joinder of parties

“(a) JOINDER OF ACCUSED INFRINGERS.—With respect to any civil action arising under any Act of Congress relating to patents, other than an action or trial in which an act of infringement under section 271(e)(2) has been pled, parties that are accused infringers may be joined in one action as defendants or counterclaim defendants, or have their actions consolidated for trial, or counterclaim defendants only if—

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“(1) any right to relief is asserted against the parties jointly, severally, or in the alternative with respect to or arising out of the same transaction, occurrence, or series of transactions or occurrences relating to the making, using, importing into the United States, offering for sale, or selling of the same accused product or process; and

“(2) questions of fact common to all defendants or counterclaim defendants will arise in the action.

“(b) ALLEGATIONS INSUFFICIENT FOR JOINDER.—For purposes of this subsection, accused infringers may not be joined in one action as defendants or counterclaim defendants, or have their actions consolidated for trial, based solely on allegations that they each have infringed the patent or patents in suit.

“(c) WAIVER.—A party that is an accused infringer may waive the limitations set forth in this section with respect to that party.”.

(2) CONFORMING AMENDMENT.—The table of sections for chapter 29 of title 35, United States Code, as amended by this Act, is further amended by adding at the end the following new item:

“299. Joinder of parties.”.

(e) EFFECTIVE DATE.—The amendments made by this section shall apply to any civil action commenced on or after the date of the enactment of this Act.

Applicability.
28 USC 1295
note.

SEC. 20. TECHNICAL AMENDMENTS.

(a) JOINT INVENTIONS.—Section 116 of title 35, United States Code, is amended—

(1) in the first undesignated paragraph, by striking “When” and inserting “(a) JOINT INVENTIONS.—When”;

(2) in the second undesignated paragraph, by striking “If a joint inventor” and inserting “(b) OMITTED INVENTOR.—If a joint inventor”; and

(3) in the third undesignated paragraph—

(A) by striking “Whenever” and inserting “(c) CORRECTION OF ERRORS IN APPLICATION.—Whenever”; and

(B) by striking “and such error arose without any deceptive intention on his part,”.

(b) FILING OF APPLICATION IN FOREIGN COUNTRY.—Section 184 of title 35, United States Code, is amended—

(1) in the first undesignated paragraph—

(A) by striking “Except when” and inserting “(a) FILING IN FOREIGN COUNTRY.—Except when”; and

(B) by striking “and without deceptive intent”;

(2) in the second undesignated paragraph, by striking “The term” and inserting “(b) APPLICATION.—The term”; and

(3) in the third undesignated paragraph, by striking “The scope” and inserting “(c) SUBSEQUENT MODIFICATIONS, AMENDMENTS, AND SUPPLEMENTS.—The scope”.

(c) FILING WITHOUT A LICENSE.—Section 185 of title 35, United States Code, is amended by striking “and without deceptive intent”.

(d) REISSUE OF DEFECTIVE PATENTS.—Section 251 of title 35, United States Code, is amended—

(1) in the first undesignated paragraph—

(A) by striking “Whenever” and inserting “(a) IN GENERAL.—Whenever”; and

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(B) by striking “without any deceptive intention”;

(2) in the second undesignated paragraph, by striking “The Director” and inserting “(b) MULTIPLE REISSUED PATENTS.—The Director”;

(3) in the third undesignated paragraph, by striking “The provisions” and inserting “(c) APPLICABILITY OF THIS TITLE.—The provisions”; and

(4) in the last undesignated paragraph, by striking “No reissued patent” and inserting “(d) REISSUE PATENT ENLARGING SCOPE OF CLAIMS.—No reissued patent”.

(e) EFFECT OF REISSUE.—Section 253 of title 35, United States Code, is amended—

(1) in the first undesignated paragraph, by striking “Whenever, without any deceptive intention,” and inserting “(a) IN GENERAL.—Whenever”; and

(2) in the second undesignated paragraph, by striking “In like manner” and inserting “(b) ADDITIONAL DISCLAIMER OR DEDICATION.—In the manner set forth in subsection (a),”.

(f) CORRECTION OF NAMED INVENTOR.—Section 256 of title 35, United States Code, is amended—

(1) in the first undesignated paragraph—

(A) by striking “Whenever” and inserting “(a) CORRECTION.—Whenever”; and

(B) by striking “and such error arose without any deceptive intention on his part”; and

(2) in the second undesignated paragraph, by striking “The error” and inserting “(b) PATENT VALID IF ERROR CORRECTED.—The error”.

(g) PRESUMPTION OF VALIDITY.—Section 282 of title 35, United States Code, is amended—

(1) in the first undesignated paragraph—

(A) by striking “A patent” and inserting “(a) IN GENERAL.—A patent”; and

(B) by striking the third sentence;

(2) in the second undesignated paragraph—

(A) by striking “The following” and inserting “(b) DEFENSES.—The following”;

(B) in paragraph (1), by striking “unforceability,” and inserting “unenforceability.”; and

(C) in paragraph (2), by striking “patentability,” and inserting “patentability.”; and

(3) in the third undesignated paragraph—

(A) by striking “In actions involving the validity or infringement of a patent” and inserting “(c) NOTICE OF ACTIONS; ACTIONS DURING EXTENSION OF PATENT TERM.—In an action involving the validity or infringement of a patent”; and

(B) by striking “Claims Court” and inserting “Court of Federal Claims”.

(h) ACTION FOR INFRINGEMENT.—Section 288 of title 35, United States Code, is amended by striking “, without deceptive intention,”.

(i) REVISER’S NOTES.—

(1) Section 3(e)(2) of title 35, United States Code, is amended by striking “this Act,” and inserting “that Act,”.

(2) Section 202 of title 35, United States Code, is amended—

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(A) in subsection (b)(3), by striking “the section 203(b)” and inserting “section 203(b)”; and

(B) in subsection (c)(7)(D), by striking “except where it proves” and all that follows through “small business firms; and” and inserting: “except where it is determined to be infeasible following a reasonable inquiry, a preference in the licensing of subject inventions shall be given to small business firms; and”.

(3) Section 209(d)(1) of title 35, United States Code, is amended by striking “nontransferable” and inserting “non-transferable”.

(4) Section 287(c)(2)(G) of title 35, United States Code, is amended by striking “any state” and inserting “any State”.

(5) Section 371(b) of title 35, United States Code, is amended by striking “of the treaty” and inserting “of the treaty.”.

(j) UNNECESSARY REFERENCES.—

(1) IN GENERAL.—Title 35, United States Code, is amended by striking “of this title” each place that term appears.

(2) EXCEPTION.—The amendment made by paragraph (1) shall not apply to the use of such term in the following sections of title 35, United States Code:

(A) Section 1(c).

(B) Section 101.

(C) Subsections (a) and (b) of section 105.

(D) The first instance of the use of such term in section 111(b)(8).

(E) Section 161.

(F) Section 164.

(G) Section 171.

(H) Section 251(c), as so designated by this section.

(I) Section 261.

(J) Subsections (g) and (h) of section 271.

(K) Section 287(b)(1).

(L) Section 289.

(M) The first instance of the use of such term in section 375(a).

(k) ADDITIONAL TECHNICAL AMENDMENTS.—Sections 155 and 155A of title 35, United States Code, and the items relating to those sections in the table of sections for chapter 14 of such title, are repealed.

(l) EFFECTIVE DATE.—The amendments made by this section shall take effect upon the expiration of the 1-year period beginning on the date of the enactment of this Act and shall apply to proceedings commenced on or after that effective date.

35 USC 2, 12, 32,
41, 103, 104, 111,
119–123, 132,
135, 143, 145,
146, 154, 157,
162, 172,
182–186, 207,
210, 257, 267.

Applicability.
35 USC 2 note.

SEC. 21. TRAVEL EXPENSES AND PAYMENT OF ADMINISTRATIVE JUDGES.

(a) AUTHORITY TO COVER CERTAIN TRAVEL RELATED EXPENSES.—Section 2(b)(11) of title 35, United States Code, is amended by inserting “, and the Office is authorized to expend funds to cover the subsistence expenses and travel-related expenses, including per diem, lodging costs, and transportation costs, of persons attending such programs who are not Federal employees” after “world”.

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(b) PAYMENT OF ADMINISTRATIVE JUDGES.—Section 3(b) of title 35, United States Code, is amended by adding at the end the following:

“(6) ADMINISTRATIVE PATENT JUDGES AND ADMINISTRATIVE TRADEMARK JUDGES.—The Director may fix the rate of basic pay for the administrative patent judges appointed pursuant to section 6 and the administrative trademark judges appointed pursuant to section 17 of the Trademark Act of 1946 (15 U.S.C. 1067) at not greater than the rate of basic pay payable for level III of the Executive Schedule under section 5314 of title 5. The payment of a rate of basic pay under this paragraph shall not be subject to the pay limitation under section 5306(e) or 5373 of title 5.”.

SEC. 22. PATENT AND TRADEMARK OFFICE FUNDING.

(a) IN GENERAL.—Section 42(c) of title 35, United States Code, is amended—

- (1) by striking “(c)” and inserting “(c)(1)”;
- (2) in the first sentence, by striking “shall be available” and inserting “shall, subject to paragraph (3), be available”;
- (3) by striking the second sentence; and
- (4) by adding at the end the following:

“(2) There is established in the Treasury a Patent and Trademark Fee Reserve Fund. If fee collections by the Patent and Trademark Office for a fiscal year exceed the amount appropriated to the Office for that fiscal year, fees collected in excess of the appropriated amount shall be deposited in the Patent and Trademark Fee Reserve Fund. To the extent and in the amounts provided in appropriations Acts, amounts in the Fund shall be made available until expended only for obligation and expenditure by the Office in accordance with paragraph (3).

“(3)(A) Any fees that are collected under sections 41, 42, and 376, and any surcharges on such fees, may only be used for expenses of the Office relating to the processing of patent applications and for other activities, services, and materials relating to patents and to cover a share of the administrative costs of the Office relating to patents.

“(B) Any fees that are collected under section 31 of the Trademark Act of 1946, and any surcharges on such fees, may only be used for expenses of the Office relating to the processing of trademark registrations and for other activities, services, and materials relating to trademarks and to cover a share of the administrative costs of the Office relating to trademarks.”.

35 USC 142 note.

(b) EFFECTIVE DATE.—The amendments made by this section shall take effect on October 1, 2011.

35 USC 1 note.

SEC. 23. SATELLITE OFFICES.

Deadline.

(a) ESTABLISHMENT.—Subject to available resources, the Director shall, by not later than the date that is 3 years after the date of the enactment of this Act, establish 3 or more satellite offices in the United States to carry out the responsibilities of the Office.

(b) PURPOSES.—The purposes of the satellite offices established under subsection (a) are to—

- (1) increase outreach activities to better connect patent filers and innovators with the Office;
- (2) enhance patent examiner retention;
- (3) improve recruitment of patent examiners;

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(4) decrease the number of patent applications waiting for examination; and

(5) improve the quality of patent examination.

(c) REQUIRED CONSIDERATIONS.—

(1) IN GENERAL.—In selecting the location of each satellite office to be established under subsection (a), the Director—

(A) shall ensure geographic diversity among the offices, including by ensuring that such offices are established in different States and regions throughout the Nation;

(B) may rely upon any previous evaluations by the Office of potential locales for satellite offices, including any evaluations prepared as part of the Office's Nationwide Workforce Program that resulted in the 2010 selection of Detroit, Michigan, as the first satellite office of the Office;

(C) shall evaluate and consider the extent to which the purposes of satellite offices listed under subsection (b) will be achieved;

(D) shall consider the availability of scientific and technically knowledgeable personnel in the region from which to draw new patent examiners at minimal recruitment cost; and

(E) shall consider the economic impact to the region.

(2) OPEN SELECTION PROCESS.—Nothing in paragraph (1) shall constrain the Office to only consider its evaluations in selecting the Detroit, Michigan, satellite office.

(d) REPORT TO CONGRESS.—Not later than the end of the third fiscal year that begins after the date of the enactment of this Act, the Director shall submit a report to Congress on—

(1) the rationale of the Director in selecting the location of any satellite office required under subsection (a), including an explanation of how the selected location will achieve the purposes of satellite offices listed under subsection (b) and how the required considerations listed under subsection (c) were met;

(2) the progress of the Director in establishing all such satellite offices; and

(3) whether the operation of existing satellite offices is achieving the purposes under subsection (b).

SEC. 24. DESIGNATION OF DETROIT SATELLITE OFFICE.

35 USC 1 note.

(a) DESIGNATION.—The satellite office of the United States Patent and Trademark Office to be located in Detroit, Michigan, shall be known and designated as the “Elijah J. McCoy United States Patent and Trademark Office”.

(b) REFERENCES.—Any reference in a law, map, regulation, document, paper, or other record of the United States to the satellite office of the United States Patent and Trademark Office to be located in Detroit, Michigan, referred to in subsection (a) shall be deemed to be a reference to the “Elijah J. McCoy United States Patent and Trademark Office”.

SEC. 25. PRIORITY EXAMINATION FOR IMPORTANT TECHNOLOGIES.

Section 2(b)(2) of title 35, United States Code, is amended—

(1) in subparagraph (E), by striking “and” after the semicolon;

(2) in subparagraph (F), by inserting “and” after the semicolon; and

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(3) by adding at the end the following:

“(G) may, subject to any conditions prescribed by the Director and at the request of the patent applicant, provide for prioritization of examination of applications for products, processes, or technologies that are important to the national economy or national competitiveness without recovering the aggregate extra cost of providing such prioritization, notwithstanding section 41 or any other provision of law;”.

SEC. 26. STUDY ON IMPLEMENTATION.

(a) **PTO STUDY.**—The Director shall conduct a study on the manner in which this Act and the amendments made by this Act are being implemented by the Office, and on such other aspects of the patent policies and practices of the Federal Government with respect to patent rights, innovation in the United States, competitiveness of United States markets, access by small businesses to capital for investment, and such other issues, as the Director considers appropriate.

(b) **REPORT TO CONGRESS.**—The Director shall, not later than the date that is 4 years after the date of the enactment of this Act, submit to the Committees on the Judiciary of the House of Representatives and the Senate a report on the results of the study conducted under subsection (a), including recommendations for any changes to laws and regulations that the Director considers appropriate.

SEC. 27. STUDY ON GENETIC TESTING.

(a) **IN GENERAL.**—The Director shall conduct a study on effective ways to provide independent, confirming genetic diagnostic test activity where gene patents and exclusive licensing for primary genetic diagnostic tests exist.

(b) **ITEMS INCLUDED IN STUDY.**—The study shall include an examination of at least the following:

(1) The impact that the current lack of independent second opinion testing has had on the ability to provide the highest level of medical care to patients and recipients of genetic diagnostic testing, and on inhibiting innovation to existing testing and diagnoses.

(2) The effect that providing independent second opinion genetic diagnostic testing would have on the existing patent and license holders of an exclusive genetic test.

(3) The impact that current exclusive licensing and patents on genetic testing activity has on the practice of medicine, including but not limited to: the interpretation of testing results and performance of testing procedures.

(4) The role that cost and insurance coverage have on access to and provision of genetic diagnostic tests.

(c) **CONFIRMING GENETIC DIAGNOSTIC TEST ACTIVITY DEFINED.**—For purposes of this section, the term “confirming genetic diagnostic test activity” means the performance of a genetic diagnostic test, by a genetic diagnostic test provider, on an individual solely for the purpose of providing the individual with an independent confirmation of results obtained from another test provider’s prior performance of the test on the individual.

(d) **REPORT.**—Not later than 9 months after the date of enactment of this Act, the Director shall report to the Committee on the Judiciary of the Senate and the Committee on the Judiciary

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of the House of Representatives on the findings of the study and provide recommendations for establishing the availability of such independent confirming genetic diagnostic test activity.

SEC. 28. PATENT OMBUDSMAN PROGRAM FOR SMALL BUSINESS CONCERNS. 35 USC 2 note.

Using available resources, the Director shall establish and maintain in the Office a Patent Ombudsman Program. The duties of the Program's staff shall include providing support and services relating to patent filings to small business concerns and independent inventors.

SEC. 29. ESTABLISHMENT OF METHODS FOR STUDYING THE DIVERSITY OF APPLICANTS. Deadline.

The Director shall, not later than the end of the 6-month period beginning on the date of the enactment of this Act, establish methods for studying the diversity of patent applicants, including those applicants who are minorities, women, or veterans. The Director shall not use the results of such study to provide any preferential treatment to patent applicants.

SEC. 30. SENSE OF CONGRESS.

It is the sense of Congress that the patent system should promote industries to continue to develop new technologies that spur growth and create jobs across the country which includes protecting the rights of small businesses and inventors from predatory behavior that could result in the cutting off of innovation.

SEC. 31. USPTO STUDY ON INTERNATIONAL PATENT PROTECTIONS FOR SMALL BUSINESSES.

(a) **STUDY REQUIRED.**—The Director, in consultation with the Secretary of Commerce and the Administrator of the Small Business Administration, shall, using the existing resources of the Office, carry out a study—

(1) to determine how the Office, in coordination with other Federal departments and agencies, can best help small businesses with international patent protection; and

(2) whether, in order to help small businesses pay for the costs of filing, maintaining, and enforcing international patent applications, there should be established either—

(A) a revolving fund loan program to make loans to small businesses to defray the costs of such applications, maintenance, and enforcement and related technical assistance; or

(B) a grant program to defray the costs of such applications, maintenance, and enforcement and related technical assistance.

(b) **REPORT.**—Not later than 120 days after the date of the enactment of this Act, the Director shall issue a report to the Congress containing—

(1) all findings and determinations made in carrying out the study required under subsection (a);

(2) a statement of whether the determination was made that—

(A) a revolving fund loan program described under subsection (a)(2)(A) should be established;

(B) a grant program described under subsection (a)(2)(B) should be established; or

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(C) neither such program should be established; and
 (3) any legislative recommendations the Director may have developed in carrying out such study.

35 USC 2 note.

SEC. 32. PRO BONO PROGRAM.

(a) IN GENERAL.—The Director shall work with and support intellectual property law associations across the country in the establishment of pro bono programs designed to assist financially under-resourced independent inventors and small businesses.

(b) EFFECTIVE DATE.—This section shall take effect on the date of the enactment of this Act.

35 USC 101 note.

SEC. 33. LIMITATION ON ISSUANCE OF PATENTS.

(a) LIMITATION.—Notwithstanding any other provision of law, no patent may issue on a claim directed to or encompassing a human organism.

(b) EFFECTIVE DATE.—

Applicability.

(1) IN GENERAL.—Subsection (a) shall apply to any application for patent that is pending on, or filed on or after, the date of the enactment of this Act.

(2) PRIOR APPLICATIONS.—Subsection (a) shall not affect the validity of any patent issued on an application to which paragraph (1) does not apply.

SEC. 34. STUDY OF PATENT LITIGATION.

(a) GAO STUDY.—The Comptroller General of the United States shall conduct a study of the consequences of litigation by non-practicing entities, or by patent assertion entities, related to patent claims made under title 35, United States Code, and regulations authorized by that title.

(b) CONTENTS OF STUDY.—The study conducted under this section shall include the following:

(1) The annual volume of litigation described in subsection (a) over the 20-year period ending on the date of the enactment of this Act.

(2) The volume of cases comprising such litigation that are found to be without merit after judicial review.

(3) The impacts of such litigation on the time required to resolve patent claims.

(4) The estimated costs, including the estimated cost of defense, associated with such litigation for patent holders, patent licensors, patent licensees, and inventors, and for users of alternate or competing innovations.

(5) The economic impact of such litigation on the economy of the United States, including the impact on inventors, job creation, employers, employees, and consumers.

(6) The benefit to commerce, if any, supplied by non-practicing entities or patent assertion entities that prosecute such litigation.

(c) REPORT TO CONGRESS.—The Comptroller General shall, not later than the date that is 1 year after the date of the enactment of this Act, submit to the Committee on the Judiciary of the House of Representatives and the Committee on the Judiciary of the Senate a report on the results of the study required under this section, including recommendations for any changes to laws and regulations that will minimize any negative impact of patent litigation that was the subject of such study.

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SEC. 35. EFFECTIVE DATE.

Except as otherwise provided in this Act, the provisions of this Act shall take effect upon the expiration of the 1-year period beginning on the date of the enactment of this Act and shall apply to any patent issued on or after that effective date.

Applicability.
35 USC 1 note.

SEC. 36. BUDGETARY EFFECTS.

The budgetary effects of this Act, for the purpose of complying with the Statutory Pay-As-You-Go Act of 2010, shall be determined by reference to the latest statement titled “Budgetary Effects of PAYGO Legislation” for this Act, submitted for printing in the Congressional Record by the Chairman of the House Budget Committee, provided that such statement has been submitted prior to the vote on passage.

SEC. 37. CALCULATION OF 60-DAY PERIOD FOR APPLICATION OF PATENT TERM EXTENSION.

(a) **IN GENERAL.**—Section 156(d)(1) of title 35, United States Code, is amended by adding at the end the following flush sentence: “For purposes of determining the date on which a product receives permission under the second sentence of this paragraph, if such permission is transmitted after 4:30 P.M., Eastern Time, on a business day, or is transmitted on a day that is not a business day, the product shall be deemed to receive such permission on the next business day. For purposes of the preceding sentence, the term ‘business day’ means any Monday, Tuesday, Wednesday, Thursday, or Friday, excluding any legal holiday under section 6103 of title 5.”.

(b) **APPLICABILITY.**—The amendment made by subsection (a) shall apply to any application for extension of a patent term under section 156 of title 35, United States Code, that is pending on, that is filed after, or as to which a decision regarding the application is subject to judicial review on, the date of the enactment of this Act.

35 USC 156 note.

Approved September 16, 2011.

LEGISLATIVE HISTORY—H.R. 1249:

HOUSE REPORTS: No. 112-98, Pt. 1 (Comm. on the Judiciary).

CONGRESSIONAL RECORD, Vol. 157 (2011):

June 22, 23, considered and passed House.

Sept. 7, 8, considered and passed Senate.

DAILY COMPILATION OF PRESIDENTIAL DOCUMENTS (2011):

Sept. 16, Presidential remarks.



ADDENDUM 5

Leahy-Smith America Invents Technical Corrections Act, Pub. L. No. 112-274,
126 Stat. 2456
(2456-2459)

2014-1525
Biogen Idec MA, Inc.
v.
Japanese Foundation for Cancer Research and Bayer Pharma AG

PUBLIC LAW 112-274—JAN. 14, 2013

LEAHY-SMITH AMERICA INVENTS
TECHNICAL CORRECTIONS

126 STAT. 2456

PUBLIC LAW 112–274—JAN. 14, 2013

Public Law 112–274
112th Congress

An Act

Jan. 14, 2013
[H.R. 6621]

To correct and improve certain provisions of the Leahy-Smith America Invents Act and title 35, United States Code.

Patents.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. TECHNICAL CORRECTIONS.

Applicability.
35 USC 298 note.

(a) **ADVICE OF COUNSEL.**—Notwithstanding section 35 of the Leahy-Smith America Invents Act (35 U.S.C. 1 note), section 298 of title 35, United States Code, shall apply to any civil action commenced on or after the date of the enactment of this Act.

(b) **TRANSITIONAL PROGRAM FOR COVERED BUSINESS METHOD PATENTS.**—Section 18 of the Leahy-Smith America Invents Act (35 U.S.C. 321 note) is amended—

(1) in subsection (a)(1)(C)(i), by striking “of such title” the second place it appears; and

(2) in subsection (d)(2), by striking “subsection” and inserting “section”.

(c) **JOINDER OF PARTIES.**—Section 299(a) of title 35, United States Code, is amended in the matter preceding paragraph (1) by striking “or counterclaim defendants only if” and inserting “only if”.

(d) **DEAD ZONES.**—

35 USC 311 note.

(1) **INTER PARTES REVIEW.**—Section 311(c) of title 35, United States Code, shall not apply to a petition to institute an inter partes review of a patent that is not a patent described in section 3(n)(1) of the Leahy-Smith America Invents Act (35 U.S.C. 100 note).

(2) **REISSUE.**—Section 311(c)(1) of title 35, United States Code, is amended by striking “or issuance of a reissue of a patent”.

(e) **CORRECT INVENTOR.**—

35 USC 135 note.

(1) **IN GENERAL.**—Section 135(e) of title 35, United States Code, as amended by section 3(i) of the Leahy-Smith America Invents Act, is amended by striking “correct inventors” and inserting “correct inventor”.

(2) **EFFECTIVE DATE.**—The amendment made by paragraph (1) shall be effective as if included in the amendment made by section 3(i) of the Leahy-Smith America Invents Act.

(f) **INVENTOR’S OATH OR DECLARATION.**—Section 115 of title 35, United States Code, as amended by section 4 of the Leahy-Smith America Invents Act, is amended—

(1) by striking subsection (f) and inserting the following:

“(f) **TIME FOR FILING.**—The applicant for patent shall provide each required oath or declaration under subsection (a), substitute

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statement under subsection (d), or recorded assignment meeting the requirements of subsection (e) no later than the date on which the issue fee for the patent is paid.”; and

(2) in subsection (g)(1), by striking “who claims” and inserting “that claims”.

(g) TRAVEL EXPENSES AND PAYMENT OF ADMINISTRATIVE JUDGES.—Notwithstanding section 35 of the Leahy-Smith America Invents Act (35 U.S.C. 1 note), the amendments made by section 21 of the Leahy-Smith America Invents Act (Public Law 112-29; 125 Stat. 335) shall be effective as of September 16, 2011.

35 USC 2 note.
Effective date.

(h) PATENT TERM ADJUSTMENTS.—Section 154(b) of title 35, United States Code, is amended—

(1) in paragraph (1)—

(A) in subparagraph (A)(i)(II), by striking “on which an international application fulfilled the requirements of section 371 of this title” and inserting “of commencement of the national stage under section 371 in an international application”; and

(B) in subparagraph (B), in the matter preceding clause (i), by striking “the application in the United States” and inserting “the application under section 111(a) in the United States or, in the case of an international application, the date of commencement of the national stage under section 371 in the international application”;

(2) in paragraph (3)(B)(i), by striking “with the written notice of allowance of the application under section 151” and inserting “no later than the date of issuance of the patent”; and

(3) in paragraph (4)(A)—

(A) by striking “a determination made by the Director under paragraph (3) shall have remedy” and inserting “the Director’s decision on the applicant’s request for reconsideration under paragraph (3)(B)(ii) shall have exclusive remedy”; and

(B) by striking “the grant of the patent” and inserting “the date of the Director’s decision on the applicant’s request for reconsideration”.

(i) IMPROPER APPLICANT.—Section 373 of title 35, United States Code, and the item relating to that section in the table of sections for chapter 37 of such title, are repealed.

Repeal.

(j) FINANCIAL MANAGEMENT CLARIFICATIONS.—Section 42(c)(3) of title 35, United States Code, is amended—

(1) in subparagraph (A)—

(A) by striking “sections 41, 42, and 376,” and inserting “this title,”; and

(B) by striking “a share of the administrative costs of the Office relating to patents” and inserting “a proportionate share of the administrative costs of the Office”; and

(2) in subparagraph (B), by striking “a share of the administrative costs of the Office relating to trademarks” and inserting “a proportionate share of the administrative costs of the Office”.

(k) DERIVATION PROCEEDINGS.—

(1) IN GENERAL.—Section 135(a) of title 35, United States Code, as amended by section 3(i) of the Leahy-Smith America Invents Act, is amended to read as follows:

“(a) INSTITUTION OF PROCEEDING.—

Petition.

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“(1) IN GENERAL.—An applicant for patent may file a petition with respect to an invention to institute a derivation proceeding in the Office. The petition shall set forth with particularity the basis for finding that an individual named in an earlier application as the inventor or a joint inventor derived such invention from an individual named in the petitioner’s application as the inventor or a joint inventor and, without authorization, the earlier application claiming such invention was filed. Whenever the Director determines that a petition filed under this subsection demonstrates that the standards for instituting a derivation proceeding are met, the Director may institute a derivation proceeding.

“(2) TIME FOR FILING.—A petition under this section with respect to an invention that is the same or substantially the same invention as a claim contained in a patent issued on an earlier application, or contained in an earlier application when published or deemed published under section 122(b), may not be filed unless such petition is filed during the 1-year period following the date on which the patent containing such claim was granted or the earlier application containing such claim was published, whichever is earlier.

“(3) EARLIER APPLICATION.—For purposes of this section, an application shall not be deemed to be an earlier application with respect to an invention, relative to another application, unless a claim to the invention was or could have been made in such application having an effective filing date that is earlier than the effective filing date of any claim to the invention that was or could have been made in such other application.

“(4) NO APPEAL.—A determination by the Director whether to institute a derivation proceeding under paragraph (1) shall be final and not appealable.”.

35 USC 135 note.

(2) EFFECTIVE DATE.—The amendment made by paragraph (1) shall be effective as if included in the amendment made by section 3(i) of the Leahy-Smith America Invents Act.

Applicability.
35 USC 135 note.

(3) REVIEW OF INTERFERENCE DECISIONS.—The provisions of sections 6 and 141 of title 35, United States Code, and section 1295(a)(4)(A) of title 28, United States Code, as in effect on September 15, 2012, shall apply to interference proceedings that are declared after September 15, 2012, under section 135 of title 35, United States Code, as in effect before the effective date under section 3(n) of the Leahy-Smith America Invents Act. The Patent Trial and Appeal Board may be deemed to be the Board of Patent Appeals and Interferences for purposes of such interference proceedings.

(1) PATENT AND TRADEMARK PUBLIC ADVISORY COMMITTEES.—

(1) IN GENERAL.—Section 5(a) of title 35, United States Code, is amended—

Appointment.
Time period.
Effective date.
Deadline.

(A) in paragraph (1), by striking “Members of” and all that follows through “such appointments.” and inserting the following: “In each year, 3 members shall be appointed to each Advisory Committee for 3-year terms that shall begin on December 1 of that year. Any vacancy on an Advisory Committee shall be filled within 90 days after it occurs. A new member who is appointed to fill a vacancy shall be appointed to serve for the remainder of the predecessor’s term.”;

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(B) by striking paragraph (2) and inserting the following:

“(2) CHAIR.—The Secretary of Commerce, in consultation with the Director, shall designate a Chair and Vice Chair of each Advisory Committee from among the members appointed under paragraph (1). If the Chair resigns before the completion of his or her term, or is otherwise unable to exercise the functions of the Chair, the Vice Chair shall exercise the functions of the Chair.”; and

Designation.

(C) by striking paragraph (3).

(2) TRANSITION.—

(A) IN GENERAL.—The Secretary of Commerce shall, in the Secretary’s discretion, determine the time and manner in which the amendments made by paragraph (1) shall take effect, except that, in each year following the year in which this Act is enacted, 3 members shall be appointed to each Advisory Committee (to which such amendments apply) for 3-year terms that begin on December 1 of that year, in accordance with section 5(a) of title 35, United States Code, as amended by paragraph (1) of this subsection.

35 USC 5 note.
Determination.
Appointment.
Time period.
Effective date.

(B) DEEMED TERMINATION OF TERMS.—In order to implement the amendments made by paragraph (1), the Secretary of Commerce may determine that the term of an existing member of an Advisory Committee under section 5 of title 35, United States Code, shall be deemed to terminate on December 1 of a year beginning after the date of the enactment of this Act, regardless of whether December 1 is before or after the date on which such member’s term would terminate if this Act had not been enacted.

(m) CLERICAL AMENDMENT.—Section 123(a) of title 35, United States Code, is amended in the matter preceding paragraph (1) by inserting “of this title” after “For purposes”.

(n) EFFECTIVE DATE.—Except as otherwise provided in this Act, the amendments made by this Act shall take effect on the date of enactment of this Act, and shall apply to proceedings commenced on or after such date of enactment.

Applicability.
35 USC 5 note.

Approved January 14, 2013.

LEGISLATIVE HISTORY—H.R. 6621:

CONGRESSIONAL RECORD:

Vol. 158 (2012): Dec. 18, considered and passed House.
Dec. 28, considered and passed Senate, amended.
Dec. 30, House considered concurring in Senate amendment.
Vol. 158 (2013): Jan. 1, House concurred in Senate amendment.



CERTIFICATE OF SERVICE

I hereby certify that on this 4th day of August, 2014, the foregoing BRIEF OF APPELLANT was filed electronically with the U.S. Court of Appeals for the Federal Circuit by means of the Court's CM/ECF system. I further certify that the foregoing was served by means of electronic mail, as well as by the Court's CM/ECF system, which should have sent a Notice of Docket Activity, upon the following counsel of record for Defendants-Appellees:

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